Substance Use Related Postoperative Delirium: A Classification, Clinical and Comparative Analysis

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Abstract

Advances in medical science and technology enable more Veterans of all ages to choose surgical interventions to treat diseases, relieve pain, regain physical functionality, and to enrich their quality of life. Surgery, however, brings the risk of postoperative delirium, a common complication of surgery. Postoperative delirium is a multifactorial syndrome that appears to be transient but sustains deleterious effects long after its resolution. Much work has been done to understand the pathophysiology of this syndrome and to find efficacious means of prevention and management. This dissertation presents a compendium of three manuscripts related to the recognition, documentation and the association of postoperative delirium with poor outcomes among Veterans, with a particular interest in those with a substance use disorder and the use of psychotropic medications. The first manuscript is a review of systematic reviews, seeking consensus on the prevention of postoperative delirium. A consensus message is challenging for a syndrome with an unresolved pathophysiology. The second manuscript is a qualitative study, exploring the perspectives of stakeholder providers, regarding the documentation of postoperative delirium in the electronic medical records. The non-recognition and under-documentation of POD present a significant barrier to establishing a baseline for the at-risk population. The third manuscript reports the results of a classification and clinical analysis of substance use related postoperative delirium. Using chart reviews to establish a baseline of incidence for postoperative delirium in our local VA, and explored the associations that might be contributory to the poor outcomes attendant to this syndrome. These investigations are preliminary to proposing hypotheses for future research to investigate interventions for the prevention, management, and treatment of postoperative delirium.

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Introduction

A Veteran primarily inspired this academic journey. At first glance, there was nothing unusual about Mr. X, a thin White male who underwent a routine hernia repair, and admitted to the surgical intensive care unit (ICU) for recovery. For three days, he was unable to eat or take oral medication (NPO) while waiting for his stomach function to return. During those three days, however, he became increasingly uncooperative, agitated, and combative. For his safety, he was placed in physical restraints. A review of the medical records revealed he had been a one pack per day smoker and used several mood-altering prescription medications. On the fourth day, he went into respiratory failure, was intubated and placed on a ventilator. The postoperative plan of care in the medical records was to "continue the pre-operative course of treatment," with no attention to his unique medical and psychiatric needs. Mr. X remained in the ICU for 14 days, until a lower level of care on a surgical floor was appropriate. There he fell and sustained a concussion, resulting in additional days of hospitalization. This encounter primed a new trajectory from bedside nursing to research when a search of the literature revealed little evidence focusing on postoperative delirium among Veterans who are prescribed psychotropic medications and those with substance use disorders. This introduction summarizes the compilation of studies and reflections that shaped this dissertation compendium.

The advances in medical science and technology enable more Veterans of all ages to choose surgical interventions to treat diseases, relieve pain, and enrich their quality of life (Abelha, 2013). Surgery brings the risks of postoperative complications, such as postoperative delirium, characterized by the sudden onset of an altered mental status, agitation, and inattention (APA, 2013). This complication is associated with increased morbidity, prolonged hospitalization, and increased mortality (Gonzales, 2009). In a systematic review of 25 studies,

Dasgupta (2006) reported the incidence of postoperative delirium to be 5% -52% of surgical patients. Although anyone of any age can have delirium, those patients aged 70 years or older appear to be more likely to sustain lingering neurological injury following major surgery (Nadelson, 2014).

When Veterans with a history of alcohol consumption undergo surgery, they are at significant risk for increased incidence of postoperative complications (Harris, 2008), as are those who use other substances including opioids, tobacco, and illicit drugs (Kork, 2010). Veterans who take psychotropic medications are also at increased risk for postoperative delirium since hospitalization and surgery both result in a sudden break in routine medication and substance use (Huyse, 2003). According to Huyse (2003) in his proposed guidelines for elective surgery, patients who take psychotropic medications (PM) and undergo surgery are at risk not only for postoperative delirium and psychological withdrawal but also relapse and recurrence of mental health problems. Furthermore, Mohamad (2008), investigating the pharmacotherapy of post- traumatic stress syndrome (PTSD) in the US reported that 80% of Veterans diagnosed with PTSD are prescribed psychotropic medications. Additionally, the 2013 National Survey on Drug Use and Health reported that in 2012, one in 15 Veterans had a substance use disorder. Pre-Vietnam Era Veterans had a 3.7% rate of substance use disorder while those who have served since September 2001 have a rate of 12.7% (SAMHSA, 2015). These high numbers of potentially at-risk Veterans warranted further investigation in the prevention, recognition, and treatment of postoperative delirium.

The Gap

The review of the literature revealed a paucity of studies on the clinical outcomes of patients with substance use disorders who undergo surgery. Though surgery itself may be the catalyst for postoperative delirium, both substance use, and surgery may put patients at even greater risk for poor clinical outcomes (Harris, 2011). The original VA research team was interested in determining the incidence of hyperactive postoperative delirium (the type seen with withdrawal) in the ICU, and convened as a community of practice, spanning across nine departments. A simple unofficial voice survey, engaging health care providers in a short face to face encounter, was conducted among surgeons and ICU nurses to obtain an anecdotal impression of incidence of postoperative delirium. The consensus among nurses was about 20% of Veterans had surgery suffered postoperative delirium; while surgeons thought 10% was a more appropriate estimate.

Once IRB approval was received, the initial research team conducted a preliminary inquiry of incidence of postoperative delirium during a six- month period, (June to December 2011) using International Classification of Disease, Ninth Revision (ICD-9 codes) WHO, 2010). The ICD-9 estimated incidence was found to be 5%. However, estimates based on treatment with the drug of choice, haloperidol resulted in a 30% incidence of postoperative delirium. The documentation and accuracy of coding for postoperative delirium using the ICD-9 codes are highly variable (Hope, 2014; Voyer, 2008). Previous studies have demonstrated a lack of correlation between ICD-9 codes and clinical documentation (Ghali, 1998; Iezzoni, 1997; Katznelson, 2010). In one study, McCarthy (2000) reported that ICD-9 codes were highly reliable for identifying myocardial infarctions, but less than 60% reliable for other diagnoses.

Since there was a scarcity of studies on the interrelationship of substance use and

postoperative delirium, the search was broadened to include all at-risk patients. The preliminary inquiry set the stage to answer some broader questions.

1) What is the level of evidence regarding prevention of postoperative delirium?
2) Why are the cases of postoperative delirium not reflected in the medical records?
3) What is the incidence of postoperative delirium for a single year time-frame at our local medical center?
4) Is there an association between psychotropic medication, substance use, together or separately and poor clinical outcomes?

In addressing the gap in the literature, this dissertation compendium focuses on three manuscripts to describe a full course of inquiry using the Donabedian structure-process-outcome- model (Donabedian, 1988) as an interpretive framework.

Conceptual Framework: The Donabedian model provides a framework for assessing the quality of patient care by examining the relationship between three dimensions; structure, process, and outcome. The structure may refer to an actual facility where the care is rendered or delivered, or where an infrastructure is established to support patient care. The process is the delivery of care, or what is done to or for the patient, e.g., a screening test or a diagnosis; the outcomes are the result of the care received or the effect of an intervention or treatment on the health status of the patient (Donabedian, 1988). For the current study, the structure of interest is the administration of quality systems that dictate the guidelines and disciplinary norms that in the literature. The process describes the culture and environment in which the professions interact and contribute to the quality of care. The outcomes are the results of the structural norms and response to the process of care.

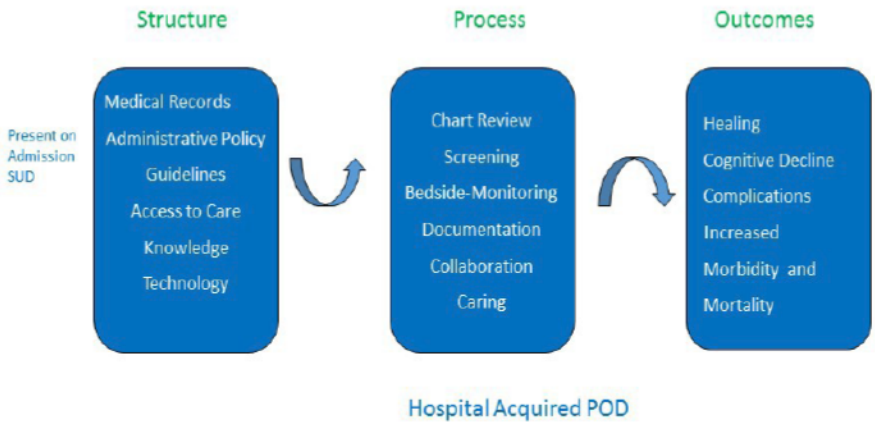

Figure 1. Conceptual Framework: Adapted from the Donabedian Structure-Process-Outcome Model

Overview

The dissertation consists of three manuscripts; 1) a review of systematic reviews investigating the consensus for the prevention of postoperative delirium. 2) a qualitative study exploring the perspectives of stakeholder providers on the documentation of postoperative delirium in the electronic medical record, and 3) a clinical review and analysis of data obtained from the EMR related to substance use and postoperative delirium among Veterans to verify the baseline documentation for hypothesis generation and future research.

Manuscript 1

Aim 1: To synthesize the existing data from systematic reviews to shape a more thorough understanding of the evidence on postoperative delirium prevention

This manuscript is a comprehensive review of systematic reviews of healthcare interventions, using the methodology as described by Smith (2011).The following research question was proffered to guide this review of systematic reviews: "What is the consensus among reviewers regarding interventions for postoperative delirium prevention?" It is essential to integrate the findings given the multiple previous studies of prevention strategies for postoperative delirium and the number of systematic reviews that evaluate investigations of this condition.

Manuscript 2

Aim *2: To explore stakeholder provider perspectives on the documentation of postoperative delirium to understand the associated facilitators and barriers.*

Given a lack of understanding about the reasons, providers identify for the under-documentation of postoperative delirium. The second manuscript presents a qualitative study of provider perspectives; Four pragmatic open-ended, semi-structured questions focused on the "how" and "why" of documentation and perceptions of postoperative delirium in interviews with each of twelve participants separately representing six departments. This format permitted the conversation to go in directions that positioned the experiences of each member as central to the answers provided. Data were analyzed using situational analysis, an extension of grounded theory first described by Clarke (2005) combined with the Donabedian process framework (Donabedian, 1988) to interpret evidence of the interpersonal aspects of clinician-patient and nurse-physician interactions that emerged.

Manuscript 3

Aim 3: *To establish the scope of postoperative delirium among Veterans by chart review, and compare the variations in accuracy of identifying postoperative delirium and substance use by ICD-9 codes and medication administration in a representative VA Medical Center.*

The third Manuscript describes a quantitative study which offers a unique opportunity to analyze data obtained from the electronic medical records (EMR) as well as administrative data to explore the accuracy of identifying postoperative delirium and examine its association with clinical outcomes. Many researchers exclude participants with known substance use from their studies; thus, the clinical outcomes of this population as they relate to postoperative delirium are under-investigated (Dasgupta, 2006). Altogether, the studies present an opportunity to generate hypotheses that may lead to more desirable clinical outcomes for patients with substance use disorder and postoperative delirium for future quality improvement strategies.

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Manuscript 1

Seeking a consensus for the Prevention of Postoperative Delirium

Abstract

Postoperative delirium is a common post-surgical complication, with deleterious consequences extending to lingering cognitive and functional impairment that can lead to institutionalization. Even with improved knowledge about its predictive and precipitating factors, the pharmacological and nonpharmacological evidence is inconsistent and sometimes contradictory. The purpose of this review is to seek consensus regarding pre-surgical interventions to prevent postoperative delirium.

Method: We searched the Medline, CINAHL, Psych INFO, Scopus, and Cochrane databases for the period from January 2010 to March 2015. Inclusion criteria were English language systematic reviews of adults with postoperative delirium.

Results: Four systematic reviews met all criteria for this review. The consensus was that multicomponent interventions are effective in preventing or reducing postoperative delirium.

Conclusions: There is a need for robust randomized controlled trials to clarify treatment and resolve management inconsistencies with pharmacological and nonpharmacological interventions, to determine which mechanisms of the multicomponent interventions are effective for which populations.

Keywords; acute confusional state, postoperative delirium, prevention, pre-surgical intervention, and review

Much work has been done to understand the pathophysiology of postoperative delirium and to discover efficacious means of prevention and management. Even though the evidence for effective preventive strategies has been confusing and sometimes contradictory, healthcare providers have an enduring and enormous responsibility to patients for preventing postoperative delirium. However, approximately 50% of elderly cardiac surgery patients and 65% of orthopedic surgery patients, continue to develop postoperative delirium (Bickel, Gardiner, Kochs, Wagner & Forstl, 2004); Burns, Gallaby & Byrne, (2004); Kazmierski, Knowman, Banach, Fendler, Okonski, & Banys 2010; Rudolph & Marcantonio 2011). The overall incidence is estimated at 36.8% to 75%, for post-surgical ICU patients (Pandharipande et al. 2008; Rudolph & Marcantonio 2011). The stress related to surgery, inflammation, and disordered neurotransmitters are thought to precipitate the complex behavioral and cognitive changes that accompany postoperative delirium (Chaput & Bryson 2012; Mantz, Hemming & Boddaert 2010). A common and devastating complication, postoperative delirium is characterized by impairment of consciousness, memory, and attention following surgery. The onset is typically sudden and fluctuates over the course of the day, with sleep-wake cycle disturbance (Burns et al. 2004; LeGrand, 2012; Mirrakhimov, Brewbacker, Krystal & Kwatra, 2014; Whitock, Vanucci & Avidan, 2011). Postoperative delirium is usually self-limiting and thought to be reversible. It is associated with an extended hospital stay, increased morbidity and mortality, poor functional recovery, and increased institutionalization for elderly surgical populations. (Burns, 2009; Rudolph & Marcantonio, 2011; Marcantonio, Palinich, Appleton, & Davis, 2011; Slor, de Jonghe, & Vreeswijk, 2011; Whitlock, et al. 2011). Moreover, in a sample of patients older than 50 years of age, investigators found an increased six-month mortality was associated with experiencing postoperative delirium (Robinson et al. 2009).

Predictions for postoperative delirium.

Despite the high incidence of postoperative delirium, 50- 80% of cases may go undetected. Clinicians have difficulty recognizing the syndrome, particularly the hypoactive motoric subtype that typically presents with lethargy and lack of attention (Ely, Stephens, Jackson, Truman & Gordon, 2004; Voyer, Cole, McCuster, St-Jaques & Laplante, 2008).Additionally, as the US population ages, the demand for surgical procedures will also increase significantly. Etzioni, (2003) forecasted a 42% increase in the demand for cardiothoracic surgery, and orthopedic surgery and urology surgery to increase by 28% to 35%, respectively, by 2020 among adults over the age of 65years. Therefore, postoperative delirium, a multifactorial syndrome that is poorly understood, will be even more significant as a clinical issue for health care providers who care for older people on the inpatient surgical units. Appropriate postoperative care of these patients involves identification of at-risk patients; awareness of the precipitating and aggravating factors that may be inherent in the environment; knowledge of the characteristics of the syndrome; and treatment for those who are severely hyperactive, and may present a safety risk for themselves and the care provider. Inouye et al. (1999) estimated the one-year healthcare cost of delirium to the nation to be in the range of $143- $152 billion. With the potential increase in at-risk patients, the need for clear and efficacious prevention and treatment is even more imperative.

Risk Factors for Postoperative delirium

In a systematic review, Dasgupta & Dumbrell, (2006), reported the risk factors for postoperative delirium following noncardiac surgery as depression, psychopathological symptoms, cognitive impairment, older age, functional impairment, pre-operative psychotropic drug use, institutionalization, sensory impairment, and greater comorbidity. Robinson et al. (2009) identified hypoxia, electrolyte abnormality, stroke, sepsis, hypoglycemia, and alcohol withdrawal as risk factors for postoperative delirium among the elderly. Although retrospective studies cannot establish causality, it is noteworthy that Burns, (2009) in a retrospective study reported a 28.9% incidence of postoperative delirium among cardiac surgery patients. Alcohol was the risk factor most closely associated with postoperative delirium in the study. Although there are many risk factors for postoperative delirium, each person has his or her risk profile, and since some factors are modifiable, rigorous screening should be undertaken to resolve or decrease the potential hazard before surgery, as specified in our national guidelines (Barr et al. 2013).

The causes of postoperative delirium are multifactorial, which makes it challenging to develop and implement standardized consensus protocols for patients at risk. However, to improve the clinical outcomes associated with postoperative delirium, systematic identification of the risk factors must occur, along with preventive measures to decrease the incidence and characteristically detrimental effects of postoperative delirium. The purpose of this review of systematic reviews is to synthesize the existing evidence to shape a more thorough understanding of strategies to prevent postoperative delirium and to determine the current consensus among reviewers about how to identify the conditions for subsequent management.

Method

Despite the multiple previous studies of postoperative delirium the number of systematic reviews that have evaluated previous investigations of the condition, a consensus message is still lacking. Thus, the following research question was proffered to guide this appraisal of systematic reviews: "What is the consensus among reviewers regarding interventions for postoperative delirium prevention?" This review followed the AMSTAR published guidelines to evaluate the methodological quality of eligible articles selected after an extensive literature search (Shea, Grimshaw, Wells, Boers, & Anderson, 2007). AMSTAR is an 11-item checklist to verify steps that should be evident in the reporting of systematic reviews as indicated in Table1.

Table 1. AMSTAR is a measurement tool created to assess the methodological quality of systematic reviews

Authors/year **Shea et al. 2006**
1. Was an 'a priori' design provided?
2. Was there duplicate study selection and data extraction?
3. Was a comprehensive literature search performed?
4. Was the status of publication (i.e. gray literature) used as an inclusion criterion?
5. Was a list of studies (included and excluded) provided?
6. Were the characteristics of the included studies provided?
7. Was the scientific quality of the included studies assessed and documented?
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?
9. Were the methods used to combine the findings of studies appropriate?
10. Was the likelihood of publication bias assessed?
11. Was the conflict of interest stated?

Search strategy:

The principal and co-investigators conducted a literature search in Medline, Cumulative Index Nursing and Allied Health Literature CINAHL, PsychINFO, Cochrane Library, and Scopus databases, supplemented by a manual search of reference lists and a search of Google Scholar. The complete search focused on review articles that concentrated on preoperative interventions aimed at preventing postoperative delirium, published from January 2010 to March 2015. The following keywords were used: postoperative delirium, acute confusional state, prevention, pre-surgical intervention, and review. The search terms included delirium, OR acute confusional syndrome, OR postoperative delirium, OR post-surgery confusion AND pre-surgical intervention, OR preoperative intervention, OR prevention

Inclusion and Exclusion Criteria:

The investigators selected studies that included adult patients published in English. The suitable review articles also had to have evaluated the prevention of postoperative delirium or postoperative complications with an emphasis on delirium, as well as specific outcomes such as postoperative delirium as a subset of postoperative complications. The investigators excluded reviews that focused on postoperative delirium in adolescents or children, as well as studies that enrolled nonsurgical patients or failed to include a comprehensive search strategy in the methods section, or a definitive accounting of included studies and their details.

Study selection:

The initial search identified 229 potentially relevant publications. After removing duplicates and reviewing the titles and abstracts, 217 titles of individual studies were excluded. The investigators retained twelve full-text review articles for more detailed evaluation. Four reviews were selected, for the current analysis. Eight full-text articles were excluded for the

following reasons: two articles did not include postoperative delirium as a variable of postoperative complication, three focused on the treatment of postoperative delirium rather than prevention, and three had no comprehensive literature search. All four articles selected for the current study described systematic reviews with also including a meta-analysis. The authors represented four different countries: South Africa, (Moyce, Rodseth & Bicard, 2014), the United Kingdom, (Partridge Harari, Martin, & Dhesi, 2014); China, (Zhang, Lu, Liu, Zou, Wang, Xu, & Shi, 2013), and Singapore (Bin Abd Razak & Yung, 2015). However, the primary studies were drawn from scientific work globally.

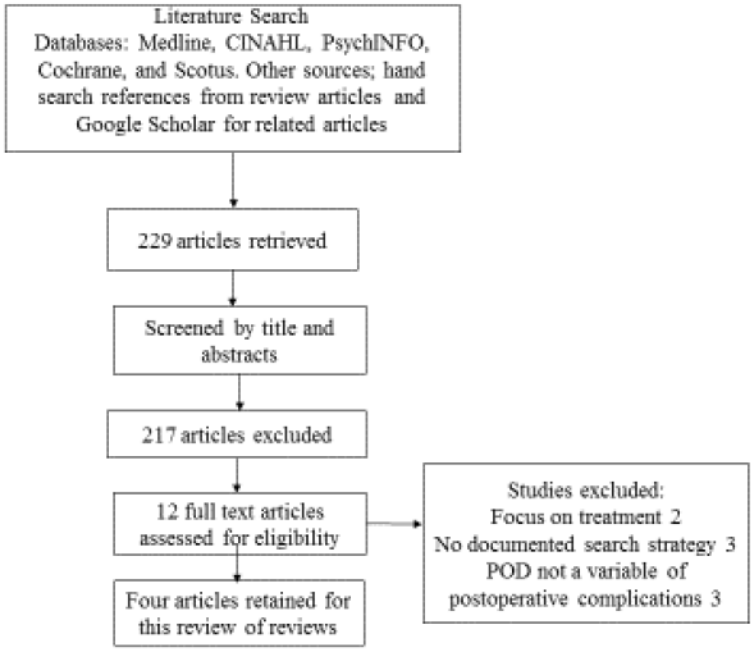

Figure1. Search Flow Diagram

Studies reviewed:

Moyce (2014) evaluated 29 studies; 19 were categorized as high quality, and the other ten had a low-quality rating of <5 on the Jadad scale. The Jadad scale is a three-item instrument that grades the presence of three specific methodological features: randomization, accountability of the patients, and blinding. The maximum score on this scale is 12, and studies with a score lower than five are considered inferior quality. Zhang et al. (2013) reviewed 38 randomized controlled trials. Three studies scored 12 on the Jadad scale, and six had scores lower than six. Abd Razak & Yung (2015) examined ten studies; three rated as Level 1, six as Level II, and one Level III. However, the tool used for evaluation was not identified. Partridge et al. did not specify the method used to assess the primary studies but discussed the methodological shortcomings. The summary of reviews reported in Table 2.

Authors for all four reviews adopted the operational definition of the Diagnostic and Statistical Manual of Mental Disorders- fourth edition (DSM- IV) (APA, 2013). Additionally; researchers identified studies that used the International Classification of Disease for delirium diagnosis (ICD-9) (Partridge et al. 2013, Bin Abd Razak & Yung, 2015). Most studies used reliable, validated instruments such as the Confusion Assessment Method (CAM) and the Intensive Care Screening Delirium Checklist (ICSDC).

Altogether, the reviewers evaluated 82 primary studies; some incorporated in more than one review. Subsequently, there were 59 unique studies. The current review of these studies addresses three types of interventions, in particular; pharmacological interventions, non-pharmacological interventions, and other single component preventive interventions.

Table 2: *Summary of Reviews*

Author /year	Designation	Primary RCTs included	Time frame of search	Quasi-experimental studies
Zhang 2013	Strategies for preventing postoperative delirium	38 RCTs 9 meta-analyses 7 single trials	Before August 2012 English language limitation	
Moyce, 2014	Perioperative interventions to decrease delirium after noncardiac surgery	29 RCT 8 meta-analyses 7 single trials	1996- 2012 English language limitation	
Partridge, 2014	Comprehensive geriatric assessment on postoperative outcomes	Two	1980 – June 2013	3 (One study reported on postoperative delirium)
Bin Abd Razak, 2015	Prevention strategies for postoperative delirium after total joint arthroplasty	Three	Up to June 2014 English language imitation	2 prospective cohort studies

Ten studies had no effect on postoperative delirium and consequently excluded from further consideration. The remaining studies in this review included patients with the following procedures; 42 orthopedic surgeries, 14 abdominal surgeries, nine non-cardiac surgeries, four thoracic, nine cardiovascular, and one spinal surgery.

The non-pharmacological strategies for prevention

Altogether, nine primary multicomponent interventions were assessed; seven interventions had positive effects, such as a reduction in the incidence of postoperative delirium, severity or duration of hospital stay. The evaluators did not always present a description of the

various constituents of the multicomponent interventions. Table 3 &5 summarizes the results.

The non-pharmacological strategies mostly described some variation of a geriatric consultation and/ or comprehensive geriatric assessment (CGA) (Lundstrom et al. 2007; Marcantonio et al. & 2001). The CGA is a multidisciplinary diagnostic or treatment plan designed to identify conditions which may lead to poor outcomes. The treatment plan addresses modifiable risk factors to facilitate more favorable clinical results. Zhang et al. (2013) reported evidence of a decrease in the incidence of postoperative delirium from a meta-analysis of two RTCs, comparing multicomponent interventions versus standard care. Moyce et al. (2014), reported on pre-operative geriatric consultation versus usual care to decrease the incidence of postoperative delirium (Deschodt et al. 2012; Marcantonio et al. 2001). Partridge et al. reported on the proactive care of older people (POPS) study that used a before-and-after intervention to show evidence of a reduction in postoperative delirium (Harari et al. 2007). POPS involved geriatric consultation and a multidisciplinary team working together in the intervention arm of the study. Bin Abd Razak reported on a single study (Radcliff et al. 2012) that found a reduction in the incidence of postoperative delirium, exploring rigorous pre-surgical risk assessment stratification versus standard reported on multicomponent preventive strategies, and all reported a decrease in the incidence of postoperative delirium.

Pharmacological strategies for prevention

Zhang was the only reviewer to report on the comparison between alpha 2 – adrenergic receptor agonists, dexmedetomidine, and clonidine versus other sedatives. Dexmedetomidine, an agent in preventing postoperative delirium, was found to be superior to the other sedatives. (Maldonado et al. 2009; Shehabi et al. 2009). The power calculations suggested that 686 subjects would be needed to see a difference in the pooled incidence, but the study had only 445

participants (Zhang et al. 2013). The different dosage for each intravenous intervention was reported for each outcome.

Antipsychotics present another pharmaceutical preventive strategy. Zhang, (2013), evaluated the use of a typical antipsychotic, haloperidol, and the atypical antipsychotics olanzapine and risperidone. Antipsychotics as a group are effective in reducing the severity and shortening the duration of postoperative delirium (Kalisvaart et al. 2005; Kaneko et al. 1999). Only Wang et al. (2012) found evidence that haloperidol was instrumental in decreasing postoperative delirium.

The Zhang, (2013) reported that the meta-analysis revealed atypical antipsychotics are superior to typical antipsychotics in preventing postoperative delirium (Kalisvaart et al. 2005; Kaneko et al. 2005; Prakanrattana & Prapaitrakool, 2007). The evaluation of the antipsychotics was also noteworthy for the variety of dosages, route of administration and the heterogeneity among the patient groups. In contrast, Moyce, (2013) evaluated haloperidol and reported a possible protection from postoperative delirium with the use of that agent. Bin Abd Razak & Yung (2015) indicated that olanzapine prevented postoperative delirium (Larsen et al. 2010) while Zhang, (2013) citing the same study, reported that olanzapine increased the severity of postoperative delirium (Larsen et al. 2010).

Both Zhang et al. (2013 and Moyce et al. (2014) evaluated the same studies on the acetylcholinesterase inhibitor, donepezil; their meta-analyses sought to determine whether the level of donepezil would have an effect on the incidence of postoperative delirium. Their analysis of prior studies showed no positive impact on postoperative delirium (Liptzin, Laki, Garb, Fingeroth & Krushell, 2005; Marcantonio, Pallhnich, Appleton, & Davis, 2011; Sampson, Raven, Ndhlovu, Vallance, Garlick, & Watts, 2007). By contrast, Bin Abd Razak & Yung,

(2015) evaluating one study (Sampson et al. 2007) reported that donepezil prevented postoperative delirium. Power calculations suggested that 794 patients per group; however, the study had 121 patients per group. Gabapentin, (usually used for seizures) versus placebo showed a positive effect, both on the incidence and severity of postoperative delirium (Akarsu, Bolat & Ozkaynak, 2012; Leung, Sand & Rico 2006) and (Pesonen et al. 2011).The same result was reported by both (Zhang et al. (2013) and Moyce et al. (2014).

The effect of anesthesia on postoperative delirium has been the subject of numerous studies. There was a total of 18 primary investigations in this area. Moyce et al. (2014) and Zhang et al. (2013) agreed that light sedation reduced the incidence of postoperative delirium during spinal anesthesia for orthopedic surgery (Sieber et al. 2010) However, when anesthesia is administered intraoperative, the evidence is less clear. Moyce et al. (2014) reported only a minor trend that favored inhalation versus intravenous anesthesia, whereas general anesthesia may have increased the risk of developing postoperative delirium (Mason, Noel-Storr & Ritchie, 2010). Zhang et al. (2013) reported additional ketamine during induction (Hudetz et al. 2009) as well as additional fascia iliac compartment block (Mouzopoulos et al. 2010) were useful in preventing delirium.

Table 3: *Summary of results of non-pharmacological interventions for postoperative delirium.*

Review	Intervention/Method	Trials	Reduction in incidence of POD	Effect on severity of POD	Effect on duration of POD
Zhang et al. 2013	Geriatric consultation vs. standard care	2 trial meta-analysis Pooled RR 0.17, (0.58-0.86) $p = 0.000$ Significant	Decrease 43.3% versus 62.4% multicomponent intervention vs. standard	Less patients with severe delirium (7/62 11.3% vs.18/64 28.1%) $p = 0.02$	No effect
	Comprehensive intervention vs. standard				Shortened the length of POD (5.0 ± 7.1 versus 10.2 ± 13.3 days. Multicomponent intervention versus standard $P = 0.009$
Moyce et al. 2014	Geriatric consultation vs. standard care	3 trials Pooled OR 0.46 (0.32-0.67) Significant	Decrease, lower incidence in the intervention group than controls in all three trials.		Geriatric consultation had no effect once delirium developed

Zhang et al. 2013	Sleep restoration using bright light therapy (2 hours/day mornings 2200- 50001 lx) compared to the standard group	2 trials Pooled RR 0.30 (0.07 -1.26) Nonsignificant	Reduced severity 6.7± 0.7 vs. 21.1 ±7, bright light versus standard
Moyce et al. 2014 & Zhang et al. 2013	Bright light therapy	2 trials Pooled OR 0.20 (0.03- 1.19 Non- significant	

POD Postoperative delirium.

Table 4: *Summary of results of pharmacological interventions for postoperative delirium.*

Review	Intervention/Method	Trials	Reduction in incidence of POD	Effect on severity	Effect on duration of POD
Zhang, 2013	Alph-2 adrenoceptors agonists (Dexmedetomidine and clonidine) compared to Propofol and midazolam	3 RTC RR 0.55 (0.23 to 1.28) Significant Subgroup analysis RR 0.39 (.16 to 0.95) Significance	Dexmedetomidine and clonidine superior to other sedatives Dexmedetomidine more effective than other sedatives including clonidine	Clonidine maintenance infusion vs. standard reduced the severity (DDS, 0.6 ± 0.7 vs. 1.8 ± 0.8) $P <$ 0.001	Dexmedetomidine Superior to Propofol (2± 4 vs. 5 ±8 days $p =$ 0.032)
Zhang, 2013	Would elevated brain levels of acetylcholinesterase (donepezil and rivastigmine) be effective for preventing POD	4 RCT RR 0.95 (0.63 to 1.44) Nonsignificant			
Moyce, 2014	Efficacy of donepezil vs. placebo, on outcome of POD	3 trials OR 0.76 (0.28, 2.06) Favors donepezil			

Moyce, 2014	Efficacy of peri-operative gabapentin vs. placebo	2 trials OR 0.07 (0.00, 1.51)	Decreased incidence of POD		
Zhang, 2013	Antipsychotics (Typical: haloperidol. Atypical: risperidone, and olanzapine) Haloperidol vs. placebo	6 trials RR 0.50 (0.34 to 0.73) Significant	Both typical and atypical prevent POD	Haloperidol vs. placebo decreased severity of (DRS, 14.40± 3.5 vs.18.41±4.4)	Shortened the duration of POD (5.41±4.91vs. 11.85±7.6 days
	Antipsychotics	Subgroup analysis: Typical RR 0.71 (0.54 to 0.93) Atypical RR 0.35 (0.26 to 0.50)	Atypical antipsychotics superior compared to typical antipsychotics.		
	Direct comparison of atypical antipsychotics, typical antipsychotics, and placebo	(estimated RR 1.95,95% CI = 1.28 to 2.96, p = 0.072) Pooled incidence 14.5% (95% CI = 12.1% to 17.3%) for antipsychotics vs. 28.4% (95% CI = 21.0% to 38.5 %) for placebo.			

	Olanzapine (atypical antipsychotics)			Olanzapine increased the severity (DRS), 16.44 ± 3.7 versus 14.5 ± 2.7
Moyce, 2013	Efficacy of intravenous versus inhalation anesthesia on outcome of postoperative delirium	3 trials OR 2.4 (0.32, 15.54) Favors inhalation	No effect on POD	
Moyce, 2013	Efficacy of haloperidol	3 trials OR 0.62 (0.36, 1.05)	Possible protection from delirium	
Zhang 2013	Comparing Neuroaxial Anesthesia vs. general anesthesia	4 trials RR 0.99 (0.65 to 1.50 Nonsignificant		
Zhang, 2013	Comparing epidural anesthesia versus intravenous analgesia	3 trials RR 0.93 (0.61 to 1.43) Nonsignificant		

Moyce, 2013	Efficacy of depth of anesthesia versus standard care Light sedation (BIS > 80) vs deep sedation	3 trials OR 2.66 (1.27, 5.56) Significant	Bispectral index (BIS) of <40 reduced the risk of developing POD (*p*=0.001) BS > 80 (during spinal anesthesia) decreased POD by 50% among orthopedic patients.
Moyce, 2013	Efficacy of general versus regional anesthesia	3 trials OR 0.76 (0.47, 1.23) Nonsignificant	

Table 5: *Single interventions; investigating incidence or severity of postoperative delirium.*

Reviewer	Author-year	Intervention/ Method	Research Design	Age	Sample size	Effect on POD	Effect on severity	Diagnostic method	Surgery type
Zhang, 2013	Musclow et al.	Long-acting morphine vs. placebo for the prevention of POD	DBRPCT		190	(10.3% vs. 3.4%) morphine vs. placebo. *P*= 0.082 No difference	Increased severity	NCS	Orthopedics
Partridge, 2014	Harari et al.	Screening pre-op to identify unmet needs vs. usual care	QES	>65	108 (I = 54) (C= 54)	Reduced incidence with screening			Elective orthopedic
Bin Abd Razak 2015	Radcliff, Et al.	To determine the effect of Preoperative screening with management vs. usual care	PCS	Mean 64.4	*623* (C= 493)	Decrease 10.4% control vs. 0.8% intervention		Designated physicians. No validated tool used	Orthopedics
Bin Abd Razak 2015	Pinter et al	The Informant Questionnaire on Cognitive Decline (IQCODE) tool to predict risk.	PCS	Mean 73.6	101	Score >50 associated with POD a 14% incidence. OR 12.7 (95% CI= 1.4 – 115.5, *p*= 0.02)		MMSE CAM	Orthopedics
Bin Abd Razak, 2015	Sultan et al.	Melatonin, clonidine, midazolam vs. placebo to prevent or treat POD	RCT	>65	300	Preoperative melatonin decrease POD. Also increased treatment effectiveness		AMT (Abbreviated Mental Test)	Orthopedics

Zhang, 2013 & Moyce, 2014	Hudetz et al.	Additional ketamine for induction vs. standard	PC	55	29	Additional ketamine had less POD. (3.45% vs. 31.03%).	ICDSC	Cardiac surgery
	Aizawa, Et al.	Clarify the effect of improving sleep-wake cycle with scheduled doses of diazepam, flunitrazepam, and pethidine (DFP) vs. standard	RCT	>70	42	Decreased incidence of POD 35% POD in non DFP patients vs. 5% in DFP patients $P = 0.023$.	APACHE score and Psychiatrist assessment	
Zhang, 2013 & Moyce, 2014	Mouzopoulos et al.	Investigated the effects of additional fascia iliac compartment block on POD.	RPCS		102	Prophylaxis group showed decrease for additional(10.8 % vs,. 23.8% vs. standard		Orthopedics
Partridge, 2014	Kudoh et al.	Continuation of antidepressant therapy vs. control		48	120 (I= 80) (C= 40)	Increased POD when antidepressant discontinued.	DSM III	Orthopedic

POD: postoperative delirium. .QES: a Quasi-experimental study. PCS: Prospective cohort study. RCT: Random control trial, RPCS: Randomized placebo-controlled study. DBRPCT: Double-blind randomized placebo-controlled trial. ICDSC, Intensive care delirium screening checklist, NCS: Neecham confusion scale

Discussion

This review revealed that many pharmaceutical interventions did not prevent or decrease the severity of postoperative delirium, and some reported results are contradictory. The only consensus among reviewers is that multicomponent interventions prevent or reduce the incidence of postoperative delirium among older patients. Although the pathophysiology of postoperative delirium remains unclear, perioperative multicomponent interventions are more likely to address some mechanisms of postoperative delirium. Consistent with the findings of this analysis of systematic reviews, the American Geriatric Association (AGS) guidelines for the prevention of postoperative delirium concur that older adult-at-risk patients would benefit most from the implementation of non-pharmacological multicomponent interventions when coordinated by a multidisciplinary team (AGS Panel, 2015). The guidelines of the National Institute of Clinical and Health Excellence (NICE) for delirium also cite the dearth of strong evidence to support single component and pharmacological interventions. The guideline strongly supports and bases its recommendations on multicomponent intervention (O'Mahony, Murthy, Akunne, & Young, 2011).

As one of the multi-component interventions, the Comprehensive Geriatric Assessment (CGA) and the geriatric consultation comprise a thorough pre-surgical assessment, along with plans for patient management and rehabilitation (Deschodt et al. 2012; Ettema, van Koeven, Peelen, Kalkman, Schuurmans, 2014). The CGA is typically used as a risk stratification tool for appraising and optimizing physical health, emotional well-being, psychological health, functional status, and social support in older patients to enhance both long and short- term clinical outcomes (Evans, et al. 2013). Usually more successful when used by interdisciplinary teams, CGA integrates planning, treatment, and long-term follow-up of pre-surgical patients (Abete et al.

2015; Dewan, Zheng, Xia, 2012). However, Partridge (2014), suggests that the use of the CGA in surgical settings is often limited to assessment, ignoring the planning, management, and rehabilitation components. Focusing on the evaluation facilitates not only the identification of co-morbidities and risk factors but also presents the opportunity for proactive planning preoperatively to include appropriate individualized care for the perioperative period. Planning should involve a multidisciplinary team to construct a multidimensional approach to decrease adverse outcomes such as postoperative delirium among older surgical patients (Dewan, Zheng & Xi, 2012). Among medical patients where CGA has demonstrated much success, both the assessment, and the individual optimization pre-surgery seem to be necessary for positive clinical outcomes (Ellis, & Langhorne, 2004).

When discussing the efficacy of multicomponent interventions, it is usually difficult to define the effective components. Studies that explore multicomponent bundles seldom address the same intervention components (Reston & Scolles, 2013). It is, therefore, challenging to examine the same set of risk factors for the prevention of postoperative delirium across studies. Moreover, all the CGA interventions in this review were conducted predominantly on orthopedic patients.

Therefore, it was difficult to decide which factors influence the reduction, severity, or duration of postoperative delirium, or whether those interventions were group specific (Reston & Scholles, 2013; Siddiqi, Holt, Ritton, & Holms 2007). There was concern among reviewers regarding the lack of standardization in the definitions of concepts, incidence, and length of postoperative delirium among the pharmacological studies. The results of those studies seldom addressed the severity of symptoms or the motoric subtypes, namely, hypoactive, hyperactive, or mixed postoperative delirium. In the pharmacological intervention studies, there was an absence of standardized dosages and route of administration. The haloperidol trials

served as a worthy example (Kalisvaart et al. 2005; Kaneko et al. 1999; Wang et al. 2012). In a meta-analysis of three studies using haloperidol, each study used a different route, different dose, and different scheduled dosage. Although the meta-analysis favored haloperidol as a preventive measure, there was a lack of guidance for clinicians regarding the relationship between the efficacy and dosage of haloperidol. Notably, the American Society of Critical Care Medicine does not support the use of haloperidol as a preventive pharmacological agent for postoperative delirium (Barr et al. 2013). A recent RCT investigating the efficacy of low dose scheduled haloperidol to prevent the progression conversion of ICU subsyndromal delirium to more severe delirium found that haloperidol had no preventive effect even though initiated early in the ICU stay (Al-Qadheeb et al. 2015). Hakim et al. (2012) also found that the atypical antipsychotic risperidone showed no effect on subsyndromal delirium.

Furthermore, the reviewers all agreed that heterogeneity among patients in the intervention groups and the various tools used to identify postoperative delirium prohibited a more sophisticated analysis. Other areas of agreement acknowledged by the reviewers were mostly methodological in nature. Moyce et al. (2014) observed that the perioperative geriatric consultation studies were of poor quality because they lacked randomization and blinding techniques, and only one study was adequately powered (Marcantonio et al. 2001). Five of the nine meta-analyses performed by Zhang et al. (2013) were reported as underpowered, as were two of the seven single trials. The underlying uncertainty is whether these underpowered studies affected the integrity of the findings. The literature supports the observation that under-powered studies may produce outcomes that are not correct, while large randomized controlled trials with thousands of participants are more likely to produce accurate results (Ioannidis, 2005). Underpowered studies tend to report more substantial effects for interventions. However, it is not

clear that larger effects for intervention are the impetus for the current abundance of underpowered studies (Turner, 2013).

Potential publication bias in the findings was related to the length of stay (Zhang et al. 2013), the literature has long held that postoperative delirium is associated with increased length of hospital stay (Ansaloni et al. 2010; Robinson et al. 2009). The meta- analysis by Zhang et al. (2013) reported the contrary, but only 18 of the included 38 trials reported on the duration of hospitalization. The inconsistent reporting of variables, such as length of stay, and the heterogeneity of the studies themselves may have contributed to the risk of bias. Moyce et al. (2014) also shared a concern for publication bias secondary to inadequate randomization and blinding in a sufficiently powered study without heterogeneity. Thus, caution is required when drawing conclusions about what the research shows. Unintended selection bias may also ensue when excluding patients who are at risk for postoperative delirium, such as patients with comorbidities or history of substance use, as well as patients who show early signs of cognitive decline and dementia. Not only does such exclusion raise the question of generalizability of the results, but it also denies the prospect of gaining a better understanding of clinical outcomes for these groups.

Limitations: As reviewers we acknowledge that despite our careful and thorough search of the literature, we may have overlooked one or more reviews on the prevention of postoperative delirium. Additionally, the content of the current analysis is constrained by the research question posed.

Conclusion: The consensus among reviewers was that multicomponent interventions show the most promise for preventing or decreasing the incidence of postoperative delirium. Future research should explore the mechanisms of the multicomponent interventions in a variety

of settings and among groups of surgical patients to determine which components work best for individual groups. There is still a need for robust RCTs to clarify inconsistencies relating to pharmacological interventions. Also, standardization of concepts and pharmacological dosages are necessary to ensure clarity of information and to make decisions about interventions or treatments. Moreover, descriptive language and testing strategies should be standardized to clarify the conclusions of researchers. Of concern, little research focused on caring for the patient with substance use problems in the perioperative period, to better understand its the role in the clinical outcomes of those who have postoperative delirium. Modifiable risk factors for post-operative delirium should be identified and addressed as preemptive action against postoperative delirium.

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Manuscript 2

Exploring the Under-documentation of Postoperative Delirium from the Perspectives of Stakeholder Providers

Abstract

Postoperative delirium is a common complication of major surgery and a predictor of functional decline and institutionalization among elderly surgical patients. Though postoperative delirium is under-documented in the medical record, the perspectives of stakeholder providers from primary to specialty services provide insight regarding its lack of recognition and documentation. This qualitative study explored concerns pertinent to the documentation of postoperative delirium to understand the facilitators and barriers from the stakeholder's perspective.

Design: Situational analysis, a form of grounded theory, was chosen to map the event from the ICU where the event occurs across the community of practice.

Setting/Participants: the purposive sample consisted of two stakeholders from each of six departments in the of one Veterans Affairs (VA) hospital involved in elective surgery: primary care, specialty clinic, anesthesia, surgery, mental health, and surgical intensive care. Four pragmatic, open-ended, semi-structured questions were used to interview each of the twelve participants.

Findings: Providers voiced concerns that patients were not forthcoming in screening for substance use and other risks for post-operative delirium. Nurses expressed feelings of being devalued within the healthcare team when their observations were over-looked. Nurses and physicians expressed concern about the recognition and lack of standardized nomenclature for postoperative delirium limiting documentation. Available validated instruments for early recognition of postoperative delirium were often not adopted into routine practice.

Conclusion: Both stakeholders and patients facing surgery, need the education to screen for modifiable risk factor. Tools that facilitate early recognition of postoperative delirium should be part of the routine clinical assessment.

Key Words: stakeholders, postoperative delirium. Perspectives, providers, documentation

The medical record should provide a trail or verification of all treatments, procedures, and responses of the patient, as well as the accountability of the healthcare provider. It also presents the occurrence and care history in an accurate time frame from admission to discharge. Even so, the incidence of postoperative delirium is frequently under-documented in the medical records (Katznelson et al. 2010), and perspectives and decision making of providers do not appear in the record. The purpose of this study was to explore the perspectives of stakeholder providers to elicit clues about the facilitators and barriers to the documentation of postoperative delirium in the electronic medical record.

Postoperative delirium is a common complication of major surgery and a predictor of functional decline and institutionalization among elderly surgical patients (Abelha et al. 2013). Increased post-operative complications, health service utilization, and mortality is also attendant to postoperative delirium (Abelha et al., 2013; Qinlan & Rudolph, 2010; Rudolph & Marcantonio, 2011). Studies that have explored the recognition rate of postoperative delirium among nurses and physicians suggest that the rate is between 20%- 50% and both retrospective and prospective studies showed that administrative databases underestimated its occurrence (Ely et al. 2004; Voyer, Cole, McCuster, St-Jaques, & Laplante, 2008).

Problem

During the last 15 years, several studies have reported discrepancies between actual and documented cases of postoperative delirium. Millisen, Foreman, Wouters, Driessen, Godderis & Abram, (2002) indicated that even with a conclusive diagnosis of delirium using diagnostic instruments at the bedside for three consecutive days, no formal diagnosis or clinical indications were documented in the medical records of the patients for those three days. More recently, of 25 cases of delirium identified at the bedside by a specialist team, nearly one-third did not have

their diagnosis reflected in the medical records, and only nine of the 25 identified cases had a delirium diagnosis explicitly documented by the physician in the medical records (Hope, 2014).

In the same 15 years, validated instruments such as the Confusion Assessment Method (CAM & CAM-ICU) 1990) and the Intensive Care Delirium Screening Checklist (ICDSC) became available to diagnosis postoperative delirium at the bedside (Inyoue et al., 1990; Bergeron, Dubois, Dumont & Dial, 2001). However, studies have reported that they have not been adopted in routine clinical practice (Andrews, Silva, Kaplan & Zimbro, 2015; Bergeron et al., 2001). The perspective of stakeholder providers concerning recognition of postoperative delirium and the use of relevant screening tools remains less described.

Moreover, surgeons use the term "postoperative " as a descriptor of conditions occurring during the postoperative period, a time sequence that ends when the physician decides the patient is stable and may leave the ICU for a lower level of care. Postoperative delirium may only be coded as a problem when the physician clearly documents that the postoperative condition is a complication (Murphy, 2009). With no clear guidelines in place, cases of postoperative delirium may be lost to the medical records

The Gap

Under-documentation has significant implications for early recognition, intervention, and treatment and, consequently, important clinical implications for patient care and desired outcomes. Providers are often less prepared to deal with postoperative delirium and its increasing clinical importance as well as its association with post-discharge worsening of quality of life, change in mental status, sleep disturbance, cognitive decline, institutionalization, and increased mortality (AGP, 2014). As long as postoperative delirium remains under-represented in the electronic medical record, it will not receive the attention required to foster interest and research

into its prevention and early intervention. We are unaware of any other study that explored stakeholder perspectives on the documentation of postoperative delirium. The perspectives of stakeholder providers in the US Department of Veteran Affairs (VA) health system, the site for this study, could deliver essential initial exploratory information for proposing interventions to improve the documentation of postoperative delirium in the electronic medical record.

Research design and methods

The qualitative approach of situational analysis was used to frame this study to permit the voices of providers across the perioperative service spectrum to produce data. The purposive sample consisted of two stakeholder provider from each of six departments in the community of practice involved in elective surgery: primary care, specialty clinic, anesthesia, surgery, mental health, and surgical intensive care. Four pragmatic, open-ended, semi-structured questions focusing on the "how" and "why" of documentation and perceptions of postoperative delirium were used to interview each participant separately. This format permitted the conversation to go in directions that positioned the experiences of each participant as central to the answers provided.

Approvals were obtained from the Institutional Review Board of the affiliated University and the Research and Development Committee of the involved VA Medical Center. Twelve digitally recorded interviews were conducted and stored securely in a password-protected, firewalled server, transcribed and then analyzed by the researcher.

Model of Data Analysis

The data analysis used situational analysis, a form of grounded theory first described by Clarke (2005). Similar to its predecessors, this method is dependent on traditional ideas of theoretical sensitivity and sampling, constant comparative methods, coding, memoing and diagramming. The initial approach to applying situational analysis to the interview transcripts was line by line open coding, using descriptive codes as temporary labels for the concepts and phrases of the interviews. We then used the temporary labels as the basis for creating the messy situational map of the human and nonhuman elements in the situation. Three types of maps distinguish situational analysis; the Situational Maps, Social Worlds/Arenas Maps, and Positional Maps. Broad categories were drawn from the maps based on the situation of concern. The analysis progressed to the Relational Analysis, which asks questions of the messy situational maps, establishing tangible links or relationships between the coded elements. Insight documented about the relationships are termed memoing (Clarke, 2005). The messy situational map, reported in Figure 1 seeks to embrace who and/or what is in the situation, and to illustrate their importance.

The Ordered Situational Map is a classification of the messy situational map using the categories suggested by Clarke (2005), reported in Figure 2. The Social Worlds/Arenas Map, represented in Figure 3, was created by placing the situation of interest within the extensive purview of the VA as a health system. The social world arenas analysis illustrates some of the circumstances that may unobtrusively influence, manage, or constrain the situation of interest. Finally, Figure 4: Positional Map 4, the analysis was completed. Nonetheless, the heart of the situational analysis is not in creating the maps, but in teasing out relationships that might remain obscure in the messy situation maps. Clarke (2005.

According to Clarke, it is the relational analysis that presents an organized and logical way to generate the memos. The memos, in turn, capture the complexities of the subject of interest hidden in the messy situational map, a web of stakeholders and relationships across the perioperative spectrum who may be involved in the prevention, screening, identification, and treatment in some way.

Findings

Four males and eight females; one Hispanic, three African Americans, and eight Whites comprised the sample. Professionally, there were four physicians and eight nurses. The age range was 32-64 years. The surgical intensive care nurses were more experienced than nurses from the other disciplines, with the longevity of 10-20 years in that area. The surgical ICU patients included primarily those who had cardiothoracic, ear nose and throat (ENT), and abdominal surgery but no orthopedic surgeries.

Many themes were evident from the analysis of the interviews; the following four major themes were chosen to identify the facilitators and barriers to documentation: 1. Territory vs. power, 2. Lack of standardization and definitive identifiers, 3. Truthfulness, and 4. Lack of Knowledge. Those four themes are discussed below within the context of salient excerpts from the interview data.

Territory vs. Power: Nurses are in charge of the territory in which the patient resides, but they have constrained power over the identification of relevant conditions or treatments for patients in that area. When asked to describe their experience with postoperative delirium, the nurses expressed feelings of being undervalued for their assessment skills when physicians did not respond to their report of changes in a patient's mental status as an observed situation. One registered nurse reported;

> … the doctors would come in and say, does not look like it (POD).They are in there for two minutes, if that long, he (the patient) could be clear for those two minutes…, but stick around for a few moments. So, I am telling them that he is all these things. I do not see it; they would say.

The same nurse returned to the subject;

> … he (the physician) walks out of the room and writes that the patient is calm, but someone looking at the (nurses) notes would see that there is a fluctuation (in mental status), which is one of the diagnostic criteria for postoperative delirium.

Another nurse described her experience this way:

> Then they (the patient) starts getting loopy, and want to go places, and they cannot remember where they are.., they pull on their lines and pull stuff out, then you end up having to restrain them. You can tell the doctors; sometimes they will tell you that you are giving them (the patient) too much medication

Another nurse reported:

> He was not oriented to person, place time or situation… This patient decided he be..(again) leaving …we talked him back into his room and his bed, we called for PRN medications but none was ordered, and nobody was able to see the patient, which led to the violent outbursts.

Nurses describe their position at the bedside as the best place to observe postoperative delirium. They also communicate the inherent difficulty of consoling patients who are experiencing a change in mental status, and the complexity of capturing their observations of patient status, activity, and behavior in the medical records. However, physicians in this study also reported challenges in determining the diagnosis and treatment of postoperative delirium. One physician stated:

> It is complicated when you have someone who is not acting right. Is it substance use withdrawal, or is it a postoperative complication?

Another physician said:

> Things are not always 100% clear. .. there are times when people are not quite sure what is going on, and that limits the documentation even more. It can be confusing since different specialties may have different opinions as

> to what it is that is going on, and that can lead to under diagnosis, and let me clarify, under-documentation.

Lack of standardization and b) **need for definitive biomedical identifiers** are two themes that are intertwined**.** The stakeholders agree that they needed to recognize the at- risk patient before surgery, although respective disciplines did not agree on how to accomplish that goal. One physician was confident that there were reliable instruments available to identify delirium, but others expressed challenges intrinsic to diagnosing postoperative delirium. One physician reflected:

> It is a difficult situation for the providers. Obviously, the magic pill is the lab test. If there were something..that would tell us that at 20, it is postoperative delirium, and anything less than that is not…then you can manage it, that would be like the Holy Grail, but that is the tricky part, right?

The same physician illustrates the contrast to cancer care where a standardized staging system was adopted, using tumor size for categorizing cancer patients.

> … there is also not great.. nomenclature for what we call things, we call it vis a vis Sundowner, withdrawals, all sort of thing like that, so there is no standardization. ..When taking care of cancer patients, we came up with the staging system, using tumor size in those events … To talk about [postoperative delirium], we have to be able to grade it, and we do not have a good way of grading … So that is one of the major issues as I see it.

Even though the stakeholder providers reveal the difficulty in recognizing postoperative delirium, the provider must also treat promptly. The complexity and inherent delay in treatment are captured in this response:

> …we try to make sure all of those physiologic things we can measure looks good; then the default …is postoperative delirium and substance use withdrawal. So it becomes somewhat of a default diagnosis. The problem then becomes what is the best way to treat… because it is the default diagnosis, it is usually the last thing that we try to treat.

Truthfulness: Nurses favor rigorous screening to establish a clear pre-admission baseline to facilitate the recognition of postoperative delirium, especially for patients who have substance use disorders. In reflecting on substance use, providers universally described patients with a history of substance use as being seldom truthful about their use. Nurses and physicians often become aware only when the delirium related to substance use withdrawal is in full bloom. The family was sometimes the only reliable source of information regarding patient's substance use. One nurse described the pattern this way:

> Usually, the patients come to us after surgery, and three days later… they go into withdrawal. Probably they have a history, of substance use, but most of them do not disclose it to the physician.

Another nurse contended:

> Our screening process is not very good, sometimes it goes unattended, It helps us to know the truth ….we know what's coming next, we may have that 24 to 48-hour window ….so I do not think all our tools are excellent

Nurses commented on the frustration of descriptive documentation not painting a true picture of the situation. Suggesting there is a loss of clarity in communication, even within the narrative.

> I do not think that it (POD) jumped out, it probably just blended in, and if you are not looking for it, you probably would not have noticed. Maybe if people knew they would document on it (POD) more, restless, agitated, that is it just one word, or disoriented, but that is not painting the picture that this person may be delirious.

Another nurse explained:

> As nurses, we are not supposed to diagnose; we are just expected to describe the behavior…in our notes, we have to say the patient is climbing out of bed, or patient confused…then it is up to the physician to document it as delirium or call in psych consult.

Lack of knowledge: Stakeholders outside the ICU, except psychiatry, expressed limited awareness of the syndrome and its deleterious effects. Their responses suggested a lack of understanding of the consequences of the syndrome by stakeholder providers who did not see beyond their territory. The stakeholders conveyed that there was a gap in education

communication about postoperative delirium across the services. Nurses in the ICU also admitted that they knew far too little about the syndrome. However, they expressed frustration with the physicians for not recognizing fluctuation of mental status and sleep deprivation in the ICU as barriers to the recognition, treatment, and documentation of postoperative delirium. One nurse reflected on sleep deprivation:

> … our patients in the ICU suffer way more than other patients because of the continuous stimulation. There is no day or night… leading to sleep deprivation… they are going for three days without sleep, and if they could just get two to three hours (of sleep), they will wake up as a new person. However, you cannot get the physicians to give you an order for something to sleep. Doctors are not here at the bedside observing that behavior, and they are not paying attention to what we are telling them. Which some do, some do not.

Nurses and physicians work together to achieve the same ends. In the present ICU, teamwork is the preferred model to achieve efficient and safe patient care. The study revealed a silent player, in that no physician mentioned nurses in their interview as part of the stakeholder provider team.

Discussion

A primary finding of this study was that some stakeholders expressed a need for a definitive tool to recognize postoperative delirium. This finding corroborates earlier studies which reported that, although there are validated tools for early recognition of postoperative delirium, those tools have not been adopted for routine use in the ICU (Andrews et al. 2015). Using validated instruments such as the CAM or the ICDSC enhance early recognition. The criteria for the diagnosis of postoperative delirium as described in the Diagnostic and Statistical Manual of Mental Disorders (DSM- V) are picked up through observations and interactions. There are eight DSM-V criteria: inattention, disorientation, hallucination or delusions, psychomotor agitation or retardation, inappropriate mood or speech, sleep-wake-cycle

disturbance, and symptom fluctuation (APA, 2013). The nurse at the bedside is ideally positioned to assess and validate the presence of these criteria and document their manifestation in the electronic record.

Our study also revealed that when their observations were not recognized as valid contributions, nurses felt devalued. Studies of nurses- physician communication in acute care have identified similar issues (Churchman, 2010; Thomas et al. 2003). However, since the time of Florence Nightingale, the conflict between physicians and nurses has been acknowledged (Kalisch & Kalisch, 1977; Hendel, Fish & Berger, 2007). Even though nurses are currently more educated and autonomous, the feelings still prevail and was expressed by both male and female nurses in this study. They felt very little appreciation of their professional knowledge and ability understand and anticipate the behavioral changes that follow the sudden onset of restlessness and agitation; nor did the nurses believe physicians understood the premium clinical skills acquired over years of intensive nursing contact with patients.

Keeping patients safe is a priority of nursing care. Effective communication combined with good teamwork is integral in the endeavor to keep hospitalized patients safe.(Manser, 2009; Sargeant, Loney, Murphy, 2008) Communication must be structured, clear, and easily understood by both physicians and nurses (Nadzam, 2009). The use of CAM could improve communication regarding patient care. If surgeon and nurses agreed to use the CAM and CAM-ICU; physicians could then include CAM in their post-surgical orders, requesting that nurses "call for CAM of 3 or 4" along the same lines as "call for systolic blood pressure greater than 140 and less than 90." An inquiry from the nurse to physician reporting a CAM of 3 would be understood, and the appropriate action taken. Using an effective tool could facilitate clear communication between stakeholders and improve the documentation of delirium.

The core of the problem, however, is that there can be no documentation if there is no simultaneous recognition of the presence of delirium. The current study revealed that there is a knowledge deficit in proactive care to prevent the occurrence of postoperative delirium. Nurses strongly favored pre-surgical screening especially for substance use, to provide a baseline against which they can compare patient behavior. Treatment for substance withdrawal delirium begins after all other possibilities are ruled out. However, substance use withdrawal is best treated early, particularly since alcohol withdrawal can be life threatening (Spies, Tonneson, Andreasson, Helander & Conigrave, 2001).

Consequently, the absence of essential components of social history in the medical record may lead to a delay in appropriate care. There seems to be an agreement among stakeholder providers that there is a need for thorough assessment and risk stratification of patients before surgery. There is strong evidence to support risk stratification as a preventive measure to decrease the incidence of postoperative delirium (Kalisvaart et al. 2006). The language used to describe postoperative delirium within ICU situations contributes to the difficulty of identifying the syndrome. If the diagnosis is considered sundowner syndrome, then treatment might be delayed. As an attribution given to older people who become confused as the day ends, sundowner has no urgency. However, the patient with a previous history of mental health disorders may, in fact, be withdrawing from psychotropic drugs not resumed after surgery, a situation named and noticed too late. These variations also suggest the need for more thorough pre-surgical assessment and risk stratification, and use of e-consults, a fertile area for further research.

The social world arenas map demonstrates the social actions within the situation. It brings into focus the intricate possibilities of movement by social entities through porous borders as they work in concert or in opposition to providing safe care to patients. The situational analysis

gives the opportunity to tell the story we can articulate most clearly. The interactions at the point of care were our biggest story.

Conclusion: As a situation arising in the process of recovery from major surgery, the occurrence of delirium is complicated by the ability of provider physicians to isolate it from other unanticipated postoperative events. The patient, however, may not escape the deleterious consequences of postoperative delirium in the situation of their recovery and potentially long after. Findings of this study suggest a variety of ways to encourage stakeholders to screen for modifiable risk factors and use the tools available to identify postoperative delirium. Without adopting evidence-based procedures or guidelines, critical care clinicians are left without a consistent means of identifying, communicating, and documenting delirium. Their colleagues across the perioperative spectrum also are left outside the discussion with a need for prevention education. There is a need to educate ICU patients about the importance of reporting their substance use and stakeholder providers about the need to detect and address delirium risks early.

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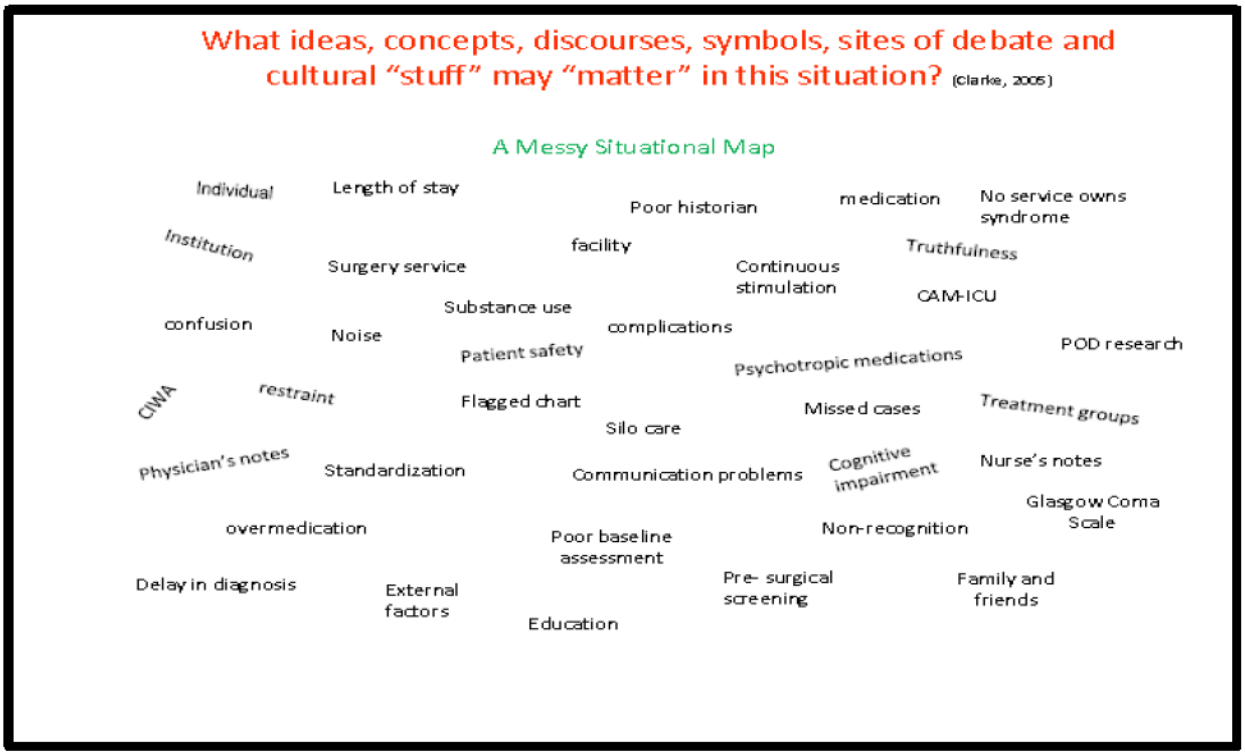

Figure 1: Section of a messy situational map

The Ordered Situational Map

INDIVIDUAL HUMAN ELEMENTS

HUMANS

Nurses, physicians SOCIOCULTURAL/SYMBOLIC ELEMENTS

Veterans

Caring is skilled professional work

Observation of ICU patients requires specialized skill and knowledge

Satisfaction goals set by institution

Substance use

IMPLICATED/ SILENT ACTORS ACTANTS

Acknowledgment of legal and illicit substance use

Under-documentation and recognition of postoperative delirium

Use of CAM-ICU

Nurses as agents for observed behavior

IMPLICATED/ SILENT ACTORS ACTANTS

Acknowledgment of legal and illicit substance use

Under-documentation and recognition of postoperative delirium

Interdisciplinary team

Satisfaction goals set by institution

Customer satisfaction

Hospital hierarchy

DISCURSIVE CONSTRUCTION OF NONHUMAN ACTANTS

Clinical Institute Withdrawal Assessment (CIWA)

Confusion Assessment Method (CAM)

Causation, incidence and outcomes of postoperative delirium

Fluctuation of postoperative delirium

SPATIAL ELEMENTS

Sleep deprivation

Truthfulness ICU

design

nurse-physician interaction

RELATED DISCOURSE (HISTORICAL, NARRATIVE, AND/OR VISUAL)

Patient and stakeholder provider education

Participants in research

Nurses as caregivers, advocates, and observers

Treatment groups

Family and friends

Poor historian

Surgeons, physicians, anesthesiologists and consults others

COLLECTIVE, pharmacists, others

Regulatory and Licensing Agencies

US Congress, NIH, Veterans Affairs

DISCURSIVE CONSTRUCTIONS OF INDIVIDUAL AND /OR COLLECTIVE HUMAN ACTORS

Patients as untruthful

Administration as insensitive

Family interactions

ECONOMIC ELEMENTS

Complications

Length of stay

Pharmaceutics

TEMPORAL ELEMENTS

Advocacy

Caring

Pre-op Interviews

Stakeholder's knowledge and clinical skills

MAJOR ISSUES

Responsiveness of physicians to reported observations

Use of multicomponent interventions

Use of early recognition instruments (CAM, ICDSC)

Pre-operative screening

Sequelae of POD

NONHUMAN ELEMENTS/ ACTANTS

Pharmaceuticals, medications, and treatments

Working knowledge of disease entity

Substance use

Synonyms for postoperative delirium

Information Technology

Figure 2: The Ordered Situational Map

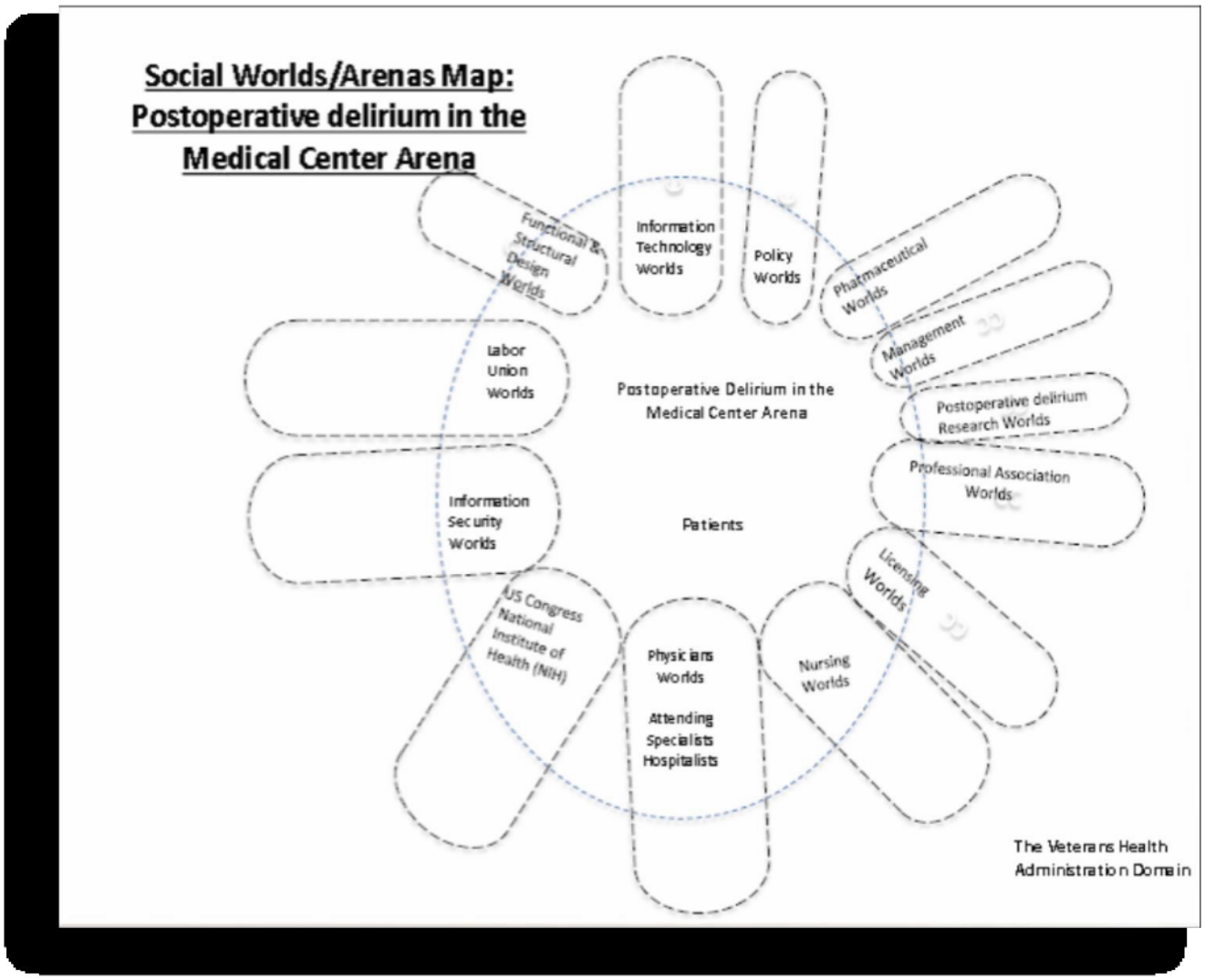

Figure 3: Social/Worlds/Arenas Map

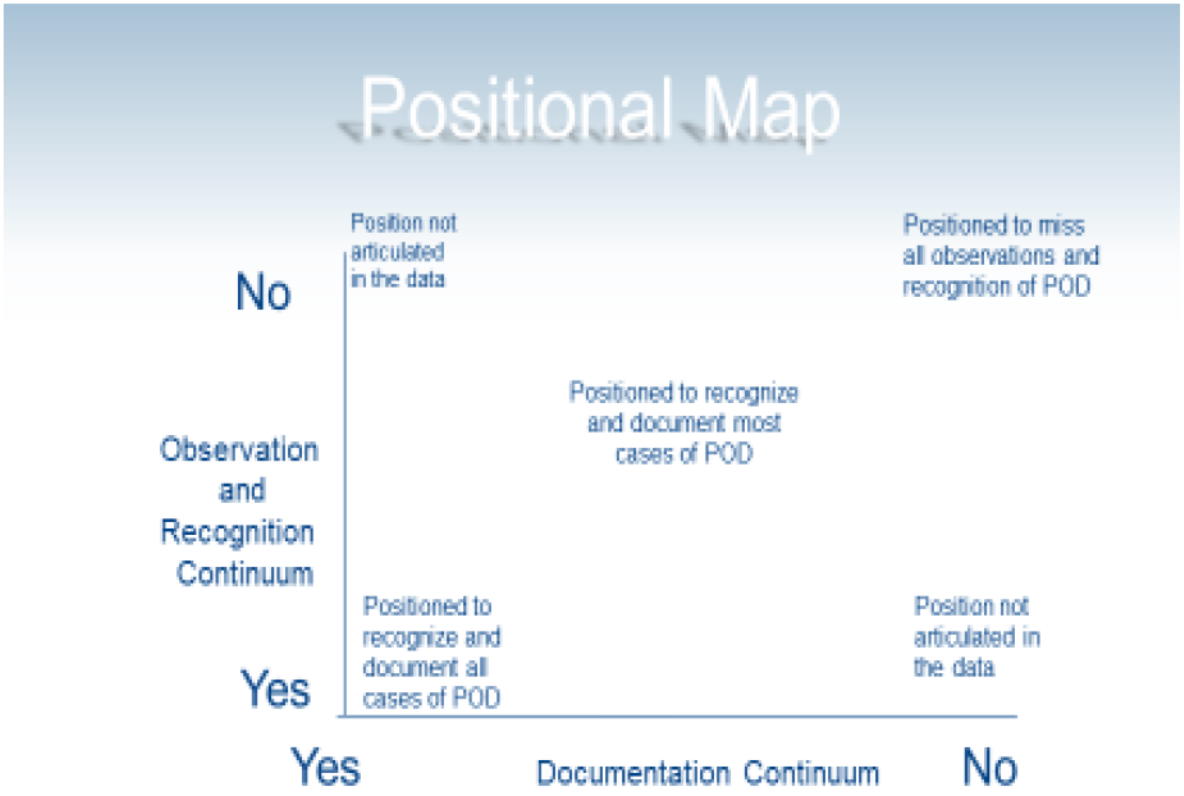

Figure 4: Positional Map: Exploring under-documentation of postoperative delirium

Manuscript 3

Substance Use Related Postoperative Delirium: A Classification, Clinical and Comparative Analysis.

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ABSTRACT

Postoperative delirium (POD) is a multifactorial syndrome that is transient but sustains deleterious effects long after its resolution. POD is characterized by altered mental status, agitation, inattention, and associated with increased morbidity, prolonged hospitalization, and increased mortality. Patients age 70 years or older appear to be most vulnerable, as are those with substance use disorders (SUD), and those who use psychotropic medications (PM).

Method: The electronic medical records, for one year (January 2010 to December 2010), were abstracted to identify POD, SUD, and use of PM and to estimate their unadjusted association with mortality, postoperative complications, ventilator events use of restraints and length of stay. Chi-square or Fisher's Exact Test were used for the binary outcomes and t-tests for the continuous variables. Sensitivity and specificity were estimated for a predetermined medication list, designated as the CCHORTL instrument.

Results: Twenty patients developed POD. CCHORTL had a sensitivity of 95.6% and specificity of 60%. POD status in length of stay, complications, ventilator events and restraints, revealed statistical significance.

Conclusion: POD requires more rigorous screening assessment and accurate documentation in the medical records.

Keywords; postoperative delirium, statistical analysis, surgical, mortality, adults.

Advances in medical science and technology enable more Veterans of all ages to choose surgical interventions to treat diseases, relieve pain, regain physical functionality, and to enrich their quality of life. Surgery, however, brings the risk of postoperative complications, such as POD. Although anyone at any age can experience POD, those age 70 years or older appear to be more susceptible to long-term neurological injury following major surgery (Nadelson, 2014). Other risk factors for delirium include cognitive impairment and substance use disorder, use of psychotropic medications, and electrolyte imbalance (Marcantonio, 2001; Dasgupta & Drumbrell, 2006). POD is a multifactorial syndrome that appears to be transient but sustains deleterious effects long after its resolution. It is associated with increased morbidity (Marcantonio, 2011) and is a predictor of functional decline and institutionalization (Visser et al. 2015).

POD is correlated with increased in-hospital mortality (4-17%) (Rudolph et al. 2007), and mortality remains elevated for three months after surgery (25.9%). Investigators found that after one to one and a half years after surgery mortality rates for patients who experienced POD was higher than for surgical patients who did not experience POD (12.7% versus 4.5%). (Gonzales, Martinez, Calderon, & Villarroel 2009; Robinson et al. 2009; Koster et al. 2009). Moreover, Gonzalez et al. (2009) concluded that the likelihood of mortality increases by 11% for every 48 hours duration of POD. Even though the detrimental consequences of POD are familiar in the literature, the recognition of delirium by healthcare providers remains challenging.

Recognition and documentation of POD

Three studies exploring the recognition and documentation rate of POD among nurses and physicians found rates that were between 20 -50% (Vollmer, 2010; Ely, 2004; Voyer, 2008). Therefore, an estimated 50-80% of cases of POD go unrecognized and untreated. In two studies,

Millisen, (2002) exploring descriptive vocabulary for delirium, and Hope et al. (2014), concurred that only about one- third of patients who have POD have their diagnosis reflected in the medical records. Moreover, only nine of the 25 confirmed cases in Hope's study (2014) had a POD diagnosis explicitly documented by a physician. To the author's knowledge, no subsequent studies have challenged that conclusion.

There are several tools to facilitate the early diagnosis of POD at the bedside, such as the Confusion Assessment Method (CAM) and the Intensive Care Delirium Screening Checklist (ICDSC) (Bergonon, 2001). In a study of 912 health professionals, Ely (2004) reported that early detection tools were not routinely adopted into clinical practice. The non-recognition and under-documentation of POD present a significant barrier to establishing a baseline for the at-risk population.

Substance use disorder is a dangerous and preventable threat to personal and public health. The at-risk group in this study consists of Veterans with substance use disorder. The Alcohol Use Disorder Identification Test (AUDIT-C) was evaluated and found adequate for recognizing pre-surgical patients with a history of risky alcohol or substance abuse. (Bradley, 2006). Illicit drugs used by Veterans also bring their unique risks to the perioperative period; cocaine has been associated with cardiac irregularities, while cannabis negatively affects the respiratory system (Bryson, 2012; Klienwachter, 2010). Additionally, Harris (2011) reported that alcohol use has consistently shown a two to six-fold increase in the occurrence of postoperative complications. Moreover, a retrospective study that examined POD among post-cardiac surgical patients found that 29% of patients had delirium, and the most common risk factor was recent alcohol use (Burns, 2009). According to Huyse (2003), in a proposed guideline for elective surgery, patients who take psychotropic medications (PM) are also at risk for POD and

psychological withdrawal as well as relapse and recurrence of mental health problems. Of the 31% Veterans diagnosed with post-traumatic stress disorder between 2003 and 2004 eighty percent had a psychotropic medications prescribed (Mohamed, 2008); moreover, documented substance use disorder among Veterans who recently served is 12.7% (NIDA, 2011).

Purpose

The full scope of POD among Veterans due to SUD and PM is thought to be greater than currently documented, yet the clinical issue is under investigated in the Department of Veterans Affairs (VA) health system (Wagner, 2009). The purpose of the study was:

1) To document the baseline occurrence of POD by chart review and compare ICD-9 codes and medication administration to determine variation in sensitivity and specificity of POD.
2) To identify SUD in a chart review based on AUDIT scores, lab tests, and substance use self-report, to estimate agreement and discord with ICD-9 codes, and POD, and also explore if SUD may be contributory to POD.
3) To explore if there are relationships between POD and variables of SUD, and PM, and their influence on the clinical outcomes of mortality, postoperative complications, ICU days, ventilator days, and use of restraints.

Conceptual Framework: The Donabedian Structure/Process/ Outcomes model (Donabedian, 1988) provides a framework for assessing the quality of care by examining the relationship between three dimensions: Structure, Process, and Outcomes. The structure may refer to an actual facility where the care is rendered or delivered or an established infrastructure that supports care. The process is the physical delivery of attention or what is done to or for the patient, e.g., a screening test or a diagnosis; the outcomes are the result of the care received or

the effect of an intervention or treatment on the health status of the patient. When applying the Donabedian framework to this study, the VA Medical Center and the EMR represent the structure, the process includes care delivered in screening recognition and treatment, and the outcomes include POD as first proximal and then leading to postoperative complications, increased morbidity, the length of stay in the hospital, and mortality. The interrelationship between structure, process and outcomes are not always conducive to high-quality health care. Though the facility may mandate screening of all patients for substance use if the instruments provided by the facility are time-consuming, and the volume of patients is overwhelming, the healthcare provider may be challenged to offer the services that could potentially result in more positive clinical outcomes. POD is the outcome of care to be measured, but first, it must be validated in the EMR as an efficient and dependable tool. One purpose of this study was to explore the variations in accuracy to identify POD in its most logical setting, the EMR.

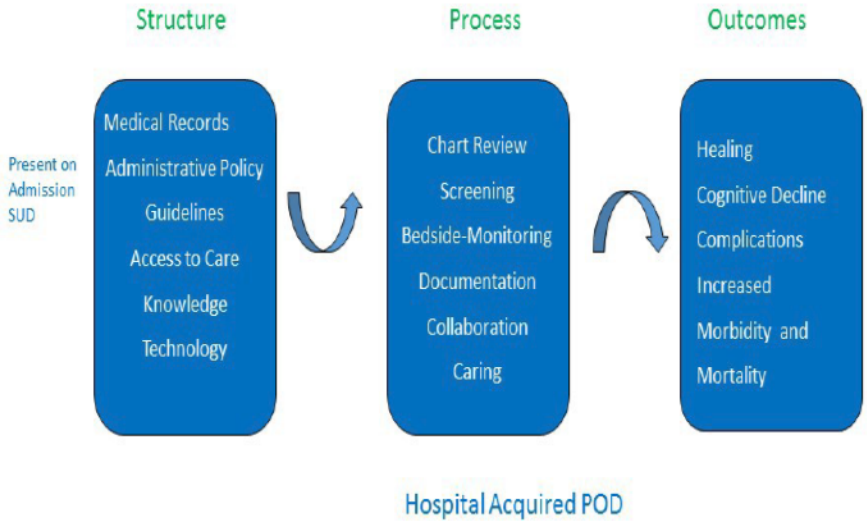

Figure1: Conceptual Framework: Adapted from the Donabedian Structure - Process-Outcomes Model

A final observation of the Donabedian framework is how the outcomes are measured; the

foundation of the quality improvement rests on the quality of the data produced by the health care professionals (Ingraham, 2010; Donabedian, 1988). Clinical records are the basic documents for studies involved in medical care processes. Therefore, medical records that are incomplete, inaccurate, or lacking documentation may downgrade the level of the outcome when evaluating outcome measures. Poorly maintained medical records also hold implications for the accuracy of incidence of POD in the present study.

Research Design and Methods

IRB approvals were granted by both the affiliated University, and VA Research and Development Committee (R &D). This retrospective study uses existing data from the VA Informatics and Computing Infrastructure (VINCI).

Sample: This study identified one sample from a past one-year period (January 2010 to December 2010). That year represents a period before the research team conducted conversations with stakeholder providers about POD, and therefore, created unique "pre-intervention" baseline data to compare with future investigations. All Veterans admitted to the Surgical ICU for post-surgery recovery during the calendar year 2010 were eligible for the study. More than 11,000 patients had surgery at the Veteran's Affairs medical center in 2010 were eligible for the study. Of those, all but 480 had same day surgery. Exclusion criteria were same-day surgery and history of dementia. The calculated sample for power is n=325.However, our final sample size was n= 251, mainly as a result of abstractor attrition during the pre-set abstraction timeline.

Measures and Chart review Protocol: Trained abstractors completed a protocol guided chart review to identify all cases of POD irrespective of cause and their corresponding ICD-9 codes. The Intensive Care Delirium Checklist (ICDSC), which retains the same diagnostic criteria as the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-V), was used to facilitate accurate abstraction of delirium data from physician and nurses bedside assessment notes. The abstractors answered the question: Is the criterion documented in the notes? The completed checklist was auto-scored by the instrument, but the final decision remained with the abstractor who decided whether lethargy was secondary to sedation rather than subsyndromal delirium. The abstractors also addressed the question: Was delirium present? Yes/no. They also abstracted Audit C scores, lab values, self-reported substance use, and psychotropic medication orders to identify patients with substance use disorder and those taking PM as well as their respective ICD-9 codes. The abstractors also captured the demographic and clinical data such as ventilator events, postoperative complications use of restraints, the length of hospital stay, and postoperative mortality.

The following checklist of medications is typically used at the study site to treat hyperactive POD as evidence of the diagnosis. The medicines: Chlordiazepoxide, Clonidine, Haloperidol, Olanzapine, Risperidone, Thiamine and Lorazepam comprise the (CCHORTL) medication checklist (Kalisvaart et al. 2005; Kenko et al. 1999; Larsen et al. 2010; Prakanrattan, 2007). The concept of CCHORTL was used to capture treatment data for the 72-hour time frame that is typically the window for postoperative delirium to occur. Some physicians used alcohol and precedex infusions proactively to treat those patients who presented on admission as SUD, to prevent them from experiencing POD.

Data requested from VINCI included mental health, vital signs, demographic

information, Medication Administration Records, and information from the Decision Support System (DSS) database. The abstractors entered their collected information directly into a REDCap data collection instrument. The REDCap data was uploaded to VINCI and merged with the VINCI data.

Data Analysis: Descriptive statistics were used to examine the distribution of values within the data set and to describe the characteristics of the sample. Descriptive statistics described and compared POD, no POD, SUD and non-SUD groups as categorized by the chart reviews. The statistics expressed regarding demographic and clinical variables using frequency distributions for binary variables means, and standard deviations for the continuous unadjusted association of POD with continuous variables estimated with Student t-tests. Unadjusted association of POD with binary variables were analyzed using chi--square or Fisher's Exact Test where appropriate. Unadjusted prevalence of POD, no POD, and SUD or no SUD - estimates were calculated for the entire population and stratified by age, race, gender, disability, and marital status. Sensitivity and specificity were also calculated for the CCHORTL instrument.

Results

There were 20 (8.4%) incidences of POD by chart review. The first case of POD occurred on day two after surgery, six cases between day two and three, eleven cases on day three. Thirteen incidences of deli occurred among Veterans who were 65years and older and seven among the younger group. The mean age of the Veterans was 61.2 years. Table 1. summarizes Age and length of stay (LOS)for the entire sample.

Table 1
Age and LOS

n=251	Age	LOS
Mean	61.2	3.88
Standard Deviation	17.50	5.97
Variance	306.0	35.72

Only three cases (1.19%) of POD were identified by ICD-9 codes, making the comparison less feasible as a means of sole documentation. CCHORTL, the medication administration checklist, reported in Table 2, was estimated to have a sensitivity of 95.65% and specificity of 60% for identifying POD in the EMR.

Table 2
Sensitivity and Specificity, CCHORTL and POD

	Delirium		**Total**
	No	Yes	
CCHORTL No	197	8	205
Yes	9	12	21
Total	206	20	

Sensitivity = 95. 65, Specificity 60%

Of the patients who had POD, three (1.2%) were identified as alcohol users. A total of seventeen Veterans (8.52%) were positive for alcohol consumption by AUDIT-C scores > four, in the chart review. Six were hazardous drinkers, with a score > eight on a maximum scale of 12 on the AUDIT scale. Sixty percent of AUDIT-C scores were missing, and 160 (61%) of the remaining subjects reported not drinking at all. One case of positive AUDIT-C associated with POD, the other two presented among those who admitted to alcohol use, but were negative on the AUDIT scale. Six Veterans who declared their alcohol use history before surgery were treated proactively with alcohol or precedex infusion. Table 3 summarizes the demographic characteristics by SUD and POD. The lack of representative ICD-9 codes for SUD prevented the estimation of the agreement and discord computations. Chi-square 2 x 2 cross-tabulation was used to explore the evidence that SUD and POD were not independent of each other. The resulting value of p 0.8147, reported in Table 5, supports that there is no indication that there is a

statistically significant relationship between POD and SUD in this sample. This study was unable to establish a relationship between substance use and POD.

Table 3
Demographics characterized by SUD and POD (frequencies [percent])

Characteristics	Overall	Delirium (POD)		Alcohol Use (SUD)		*P* value
	N=251	Yes	No	Yes	No	
Age						<.0001
>65	157 (62.5)	13 (5.17)	144 (57.4)	17 (20.73)	140 (55.8)	
< 65	94 (37.45)	7 (2.88)	87 (34.6)	8 (9.76	86 (34.3)	
Gender						<.0001
Male	243 (96.81)	20 (8.23)	223 (88.4)	24 (29.27)	199 (79.2)	
Female	8 (3.19)	0	8 (3.9)	1 (1.22)	7 (2.88)	
Race						<.0001
Black	76 (32.62)	4 (1.75)	72 (28.7)	7 (9.09)	69 (27.5)	
White	149 (65.35)	14 (6.14)	153 (60.9)	14 (18.18)	135 (90.6)	
Other	4 (1.75)	0		0		
Disability						0.187
>50%	102 (38.9%)	8 (3.29)	94 (92.2)	29 (35.37)	73 (71.6)	
<49%	160 (61.1%	12 (4.94)	148 (92.5)	53 (64.63)	107 (66.9)	
Marital Status						<.0001
Married	137 (54.58)	14 (5.76)	112 (81.8)	11 (13.42)	126 (92)	
Never married	27 (10.76)	3 (1.23)	24 (88.9)	3 (3.66)	24 (88.9)	
Separated	16 (6.37)	0	16 (100)	1 (1.22)	15 (93.75)	
Widowed	16 (6.37)	1 (0.41)	15 (93.8)	2 (2.44)	149 (87.5)	
Divorced	55 (21.91)	2 (0.82)	53 (96.4)	8 (9.76)	47 (85.5)	

Table 4.
Frequency and Chi-square values of outcome variables

Characteristic	Overall N =251	No POD POD		Chi-Square	*P* value	Missing data %
Deceased	46 (18.33)	40 (15.95)	6 (2.4)	1.7403	0.187	
Vent event	6 (2.4)	3 (1.25)	3 (1.33)	12.93	0.0003	
Complication	22 (8.8)	15 (6)	7 (3.55)	12.74	0.0004	22%
Restraints	12 (4.8)	4 (1.59)	8 (4.30)	44.57	<.0001	26%
SUD/ Audit	25 (10)	22 (8. 8)	3 (1.33)	0.8147	0.8147	68%
Psych meds	3 (1.2)	2 (0.8)	1 (0.4)	2.1305	0.31444	18%

There were three (1.33%) ventilator events for patients who experienced POD. Eight (4.30%) patients experiencing POD was physically restrained, as well as four patients (2.56%) who were not experiencing POD. Of the 20 patients with POD, seven (35%) had complications of surgery, compared to 15 (6.8%) among those who did not have POD. Altogether, 46 (19.9%) of the cohort were deceased by December 31, 2010. Six (30%) of the 20 who experienced POD died in the same period. Table 4 summarizes the Chi-square, and Fishers Exact tests results.

Chi –square test was used to verify if there is evidence to support an unadjusted association between any complication and POD. The 2x2 cross-tabulation result showed strong evidence that POD and complications are not independent of each other. In our study, 35% of those who experience delirium also have a complication.

Table 5.

Complication and POD Crosstabulation

	POD		**Total**
Complications	No	Yes	
No	162 82.3 92.57 91.53	13 6.60 7.43 65.00	175 88.83
Yes	15 7.61 68.18 8.47	7 3.55 31.82 35.00	22 11.17
Total	177	20	197
	88.89	10.15	100

χ^2 (1, n =251)= 12.74, p= .0004, phi = .54

The variable length of stay is a continuous variable. A.two sample t-test was performed to determine if there was any difference in the mean duration of stay between, those with POD and No POD, reported in Table 6. The result showed that those who experience POD had statistically significantly higher mean length of stay than those who did not. The mean length of stay for the POD group is 8.055 ±2.9, as oppose to the non-POD group of 3.88 ± 2.9, t (250) = -2.574, p=.0106. Therefore, the patient with POD could potentially have a hospital stay twice as long as the counterpart who did not experience POD.

Table 6.

Two sample t –test length of stay

	Means	Std. Dev	95% CI	
No POD	3.888	5.976	3.11	4.65
With POD	8.05	12.42	1.87	14.23

CI:= Confidence Interval, p =.0106

This study revealed that POD has a statistically significant relationship with length of hospital stay, postoperative complications, ventilator events and restraints. The medication administration checklist designated as CCHORTL has a sensitivity of 95.6% and specificity of 60% for identifying POD in the medical records.

Discussion

The reported range of incidence of POD varies widely. In a prospective study (n= 8,792), Krzych (2013) reported an incidence of 4.1% of POD among cardiac surgery patients, while Shi, (2010) reports an incidence of 44% among non-cardiac surgery patients. The sample in this study represented both cardiac and non-cardiac surgeries; the impact of POD was 20 (8.4%), which is at the lower end of the spectrum. In a review of 25 primary studies, Dasgupta & Dumbrell, (2006) presented a range of 5- 15% of surgical patients. The incidence of POD trends slightly higher with increasing age, but the mean age of this sample is 62.23, which is slightly younger than the 15- 50% incidence (Rudolph, 2011: Inouye, 2006) reported for patients over 65 years. Lundstrom, (2013) reported 52% incidence of POD in patients older than 70 years. Older patients admitted to ICU may have an incidence ranging from (The low incidence in the current study may also be related to the small sample size and missing documentation inherent in chart reviews.

The identification of POD by chart review was preliminary to performing the comparisons between ICD-9 codes and the CCHORTL medications to determine variations in accuracy. There were too few ICD-9 codes (1.14%) abstracted to make the comparison statistically feasible. The absence of ICD-9 codes representing POD may be directly related to the non-recognition of the neuropsychiatric syndrome. According to recent studies, only one-third of POD cases are reflected in the medical records (Hope, 2014; Voyer, 2008). Three studies exploring the recognition, and documentation rate of delirium among nurses and physicians found the rate is between 20 -50% (Ely, 2004; Voyer, 2008). Therefore, 50-80% cases of POD go unrecognized and potentially untreated. To generate an ICD-9 code, the physician must explicitly document that there was a postoperative complication. In the Hope et al. (2014) study, only nine cases were explicitly documented by the physician, of the 25 independently identified.

Of the seven CCHORTL medications, haloperidol and lorazepam were used most frequently to treat the severe agitation, delusion, and perceptual disturbance characteristic of postoperative delirium in this study. Thiamine is prescribed for suspected hazardous alcohol use, because typically alcoholics are lacking in vitamin B, and it is a prophylaxis to prevent Wernicke's syndrome (Day, 2013; Dobrydnjov, 2013). Thiamine acted as a marker for alcohol and identified two of the three cases found by chart review. CCHORTL proved to be very efficient in identifying patients with hyperactive POD CCHORTL, which has a sensitivity of 95.5% in identifying POD and 60% specificity in the identification of those who do not have POD, may prove potentially useful as a tool for POD identification in medical records.

The premise that SUD had implications for POD was central to the study. The mandatory annual AUDIT–C scores, lab tests, and other self-report served as the basis for identifying SUD. However, 160 AUDIT–C records missing; the lab data requested from VINCI were not available. Some self-report and AUDIT-C scores were sometimes contradictory, but behavior does change over time. Altogether, the substance use data was inadequate for the sample size, coupled with the paucity of ICD-9 codes; accurate determinations were difficult.

The AUDIT–C test has been mandated in the VA since 2006 (Bradley, 2011) to document alcohol use among Veterans. While evaluating interventions for unhealthy alcohol use in the VHA, Williams (2014), found that clinicians expressed discomfort with having conversations about alcohol with patients. They were also unaware that alcohol screening and the brief interview were a mandate of the VHA, contributing to even more constrained screening. The significant amount of missing records may indicate that there remains a less than efficient system for obtaining the AUDIT-C and substance use information. Ultimately, there was no statistical significance between POD and SUD, as reported in Table 4. There was also no statistical significance between PM and POD.

Previous studies have identified that patients who experience POD also have extended hospital stay (Maldanado, 2009). Our study also corroborated this finding. Both complications and length of hospital stay are complimentary to each other since a complication forges longer recovery time in the hospital. POD itself as a complication of surgery is attendant with poorer outcomes for the patient (Rudolph,2009). Complications and increased length of stay have implications for the higher cost of care and rehabilitation (Leslie et al. 2008). Lingering complications and extended duration of stay may also be a predictor for institutionalization (Visser, 2015), an important observation especially since the prevalence of POD increases with

age (Gani et al. 2013). Currently, 62.3% of Veterans are between the ages of 55- 64 and 19.5% are over 65 years old (Labor, 2015), suggesting attention to risks associated with age requires attention. Each year in US hospitals, at least 20% of the 12.5 million patients over 65 years of age experience complications as a direct outcome related to delirium (US. Dept. HHS).

Three of the 20 patients that experienced POD was placed on ventilators. Usually, patients on ventilators are physically restrained. However, placement on the ventilator is another factor that extends the length of hospital stay but is essential if the patient needs a high level of respiratory support. Norkiene et al. (2013) reported findings that two variables independently associated with POD development were LOS and duration of mechanical ventilation. The patient on a mechanical ventilator is at greater risk for unrecognized hypoactive POD, especially in intensive care units where validated early detection tools are not part of routine neurological assessment (Ely, 2004).

The ability to address modifiable risk factors before surgery may be a meaningful way to resolve or reduce postoperative complications, especially delirium. Implications are clear from the Donabedian Structure- Process- Outcomes Model that the process influences the outcomes. The ability to promptly detect or recognize the presentation of postoperative delirium is of paramount importance because only then will diagnosis be possible and early treatment more probable.

Limitations: As more researchers use medical records for their data, the accuracy of the documentation to reconstruct hospitalizations will become increasingly important. The paucity of ICD-9 codes reflecting substance use and postoperative delirium, as well as discrepancies between treatment and corroborating narrative, points to inadequate documentation. Over 20% of data was missing for restraints and postoperative complications, 18% for SUD and PM. Only two

records of education history were in the EMRs; 249 education records were missing. There was a total of 27 (10.3%) employment histories of the Veterans in the medical records. Poor documentation not only misrepresents the work the health providers perform on a daily basis, but it also weakens the case in this study for the prevalence of POD in our local medical center.

The inability to achieve our pre-designated sample size because of abstractor attrition was unfortunate; a more robust sample size may have constructed different results among the dependent variables.

Directions for future research: The immediate plan is to follow retroactively the 14 Veterans (six are already deceased) identified in the study for 12 months post their individual discharge date, to examine the health care utility, mortality and the cost to society compared to those who did not experience delirium during their hospital stay. Collaboration is planned with stakeholder providers to encourage intervention development to address the urgent need for education regarding screening, risk stratification, and post-surgical management of Veterans to prevent POD.

Conclusion: There is evidence that the deleterious effects of postoperative delirium are present in the local medical center. The rapid recognition of postoperative delirium requires more education for health providers, more rigorous screening, and the use of early detection instruments to facilitate the early diagnosis and treatment.

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Summary and Conclusion

The dissertation consists of three manuscripts. The first, a review of systematic reviews, investigated if there was a consensus among reviewers regarding the prevention of postoperative delirium. The second manuscript explored the perspectives of stakeholder providers concerning the under documentation of postoperative delirium. The third manuscript is a retrospective cohort study that used chart review. The study documented the baseline incidence of postoperative delirium; (POD), substance use disorder (SUD) and psychotropic medications (PM), explored the variance of accuracy between two measures against the chart reviews, and the associations of POD, SUD, and PM with clinical outcomes. The content of the dissertation is a basic inquiry to generate hypotheses for future research and interventions for the prevention and or decrease in the incidence of postoperative delirium among Veterans with substance use disorder.

The first manuscript representing the structure in the Donabedian Process Model is significant because it sought to provide a consensus message about the prevention of postoperative delirium. Many researchers have explored the subject matter and proposed numerous efficacious strategies. However, the research conclusions were sometimes contradictory and inconsistent. Four systematic reviews met the inclusion criteria of the review of systematic reviews. The findings suggest that very few pharmaceutical strategies prevent postoperative delirium. Most pharmaceuticals are effective only after the symptoms of POD are evident. The most promising of the prevention strategies are the multicomponent interventions (Reston & Scholles, 2013; Partridge et al. 2014). Even so it is hard to determine which components of the multicomponent intervention is the responsible for the positive or adverse effect and which population would derive the most benefit.

The use of multicomponent studies is supported as best practice by the American Geriatric Society in their guidelines for postoperative delirium. (AGSEP, 2015). The success of multicomponent intervention studies seems to be dependent on intrinsically engaged multidisciplinary teams, strategic risk stratification and screening before surgery with substantive pre-surgical management plans. Substance use as a modifiable risk factor was not discussed in the systematic reviews nor was the education of patients given a high priority in the primary studies. Modifiable risk factors for post-operative delirium should be identified and addressed as proactive action against postoperative delirium.

Future research should explore the mechanisms of the multicomponent interventions in a variety of settings and among groups of surgical patients to determine which components work best for individual groups. There is still a need for robust RCTs to clarify inconsistencies relating to pharmacological interventions. Also, standardization of concepts and pharmacological dosages are necessary to ensure clarity of information and to make decisions about interventions or treatments.

The second manuscript explored the perspectives of stakeholder providers concerning the under documentation of postoperative delirium in the electronic medical records (Katznelson, 2010).The qualitative approach of situational analysis an extension of grounded theory first described by Clarke, (2005) was used to frame this study to permit the voices of providers across the perioperative service spectrum to produce data. The purposive sample yielded twelve semi-structured interviews that positioned the experiences of each participant as central to the answers provided. This study was an important addition to the compendium because it amplified the process as described in the Donabedian Structure- Process- Outcomes Model.

The interviews revealed some of the intricacies involved in the course of delivering care.

The range of perspectives across six departments participating in the care of pre-surgical and surgical patients exposed that conversations about downstream problems not being shared with all stakeholder providers. One stakeholder observed that things can get very confusing when providers from different specialties may have different opinions about what is going on with the patient, a situation that may lead not only to under diagnosis but under- documentation.

One core conclusion is that there can be no applicable documentation without simultaneous recognition of the presence of the operationally defined criteria that identify postoperative delirium. The current study discovered that there is a knowledge deficit in proactive care to prevent the occurrence of postoperative delirium. Nurses and physicians strongly favored pre-surgical screening especially for substance use, to provide a baseline against which they can evaluate changes in patient status. One interesting divergence was evident; physicians still wish for a lab test or some other visible measure to define postoperative delirium while nurses are acknowledging that they recognize postoperative delirium when they see it, but they are not allowed to label it.

Nurses have an advantage of being at the bedside where they can observe the changes in behavior and mental status. Issues of communication were fundamental to how nurses perceived themselves in relationship to surgeons.

Nadzam (2009) suggests that communication must be structured, clear, and easily understood by both physicians and nurses. One of the contributory factors in this situation may be that the stakeholder providers do not use a diagnostic tool such as Confusion Assessment Method CAM for early identification of POD (Wang, 2010). The use of a tool facilitates clear communication across disciplines. There is also a need for all-around education for all stakeholder providers regarding the deleterious effects of this syndrome and teaching for patients

regarding the risk factors for postoperative delirium and what they might do to prevent it.

The third manuscript of the compendium provided the opportunity to explore the outcomes resulting from the process or treatment that was administered by the stakeholder providers. This study generated baseline documentation of POD, SUD, and PM in chart reviews. The data produced by the chart review and the data from VINCI were merged and analyzed. The analysis showed that postoperative delirium was present in the sample at 8.4% percent, and although there was no correlation between alcohol use and postoperative delirium in our study, this corroborates some previous studies (Dasgupta, 2006), while not supported by others (Marcantonio, 2001). Our study sought to identify correlations between POD, SUD, PM and clinical outcomes but we could not demonstrate significance in those relationships. There was a significant association between POD, the length of hospital stay, restraint, ventilator events and postoperative complications. ICD-9 codes and PM were not effective in predicting POD and did not appear to influence the clinical outcomes of those with POD or those without POD. CCHORTL demonstrated a high degree of accuracy in identifying the incidence of POD in the EMR.

Limitations:

The most significant limitation had to lower the sample size of the study from 325 EMRs to 251 because of abstractor attrition. The smaller sample size returned meaningful results, but a more robust sample size may have constructed different results among the dependent variables. Chart reviews are inherently challenging because of missing information, and our experience with our chart review found the same difficulty. Using the ICD-9 codes as a potential measure of the incidence of POD was considered feasible, but those ICD-9 codes were not in the EMRs. It is hard to determine a reliable source for alcohol use. Information about substance use given at

different points of interaction, are inconsistent, and frequently not congruent with the AUDIT-C score. The annual mandated test was sometimes not completed.

Implications for practice:

The results of the studies in this dissertation point to several factors that might be important in clinical practice. Few studies discussed the sequelae of postoperative delirium as it relates to the patient with substance use disorder. The use of multicomponent intervention has been shown to be effective in preventing and reducing the incidence of postoperative delirium. Partridge, (2014) observed that the success of these multicomponent interventions was less robust in surgical situations than medical because there was less attention paid to planning and management of the patient post-surgery.

Nurses may need to be more proactive at the bedside using instruments, such as CAM or CAM-ICU, that facilitate early recognition of postoperative delirium and physicians may benefit from using the measurement generated by those instrument as criteria so that communication between the two disciplines may be more meaningful. Once the CAM score is generated and documented, fewer cases of postoperative delirium will be missed.

There is also need for more efficient screening for risk factors such as cognitive impairment, polypharmacy, functional ability, and substance use to identify those at risk for postoperative delirium. Patients will benefit from additional education. Screening for substance use especially alcohol has always been demanding. New strategies should be developed to persuade patients that it is in their interest to disclose their substance use to their health care providers, before undergoing surgery.

Research Trajectory:

While stakeholder providers continue to see the incidence of postoperative delirium in the ICU, it is prudent to investigate if there may be other factors that may be contributing to the precipitation of POD among the Veterans. Additionally, the implementation of an optimization clinic to study before-and-after interventions addressing screening for substance use, risk stratification and post-surgical management of at-risk patients may prove valuable in reducing the incidence of postoperative delirium.

Summary: The first manuscript representing the structure in the Donabedian Process Model is significant because it sought to provide a consensus message about the prevention of postoperative delirium. The consensus was that multicomponent intervention is effective in preventing postoperative delirium. The second manuscript explored the perspectives of stakeholder providers concerning the under documentation of postoperative delirium in the electronic medical records. The use of early detection tools to recognize postoperative delirium would help to facilitate clear communication across disciplines. There is also a need for education for all stakeholder providers. The third manuscript of the compendium provided the opportunity to explore the outcomes resulting from the process or treatment that was administered by the stakeholder providers. This study generated baseline documentation of POD, SUD, and PM in chart reviews.

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Appendices

Appendix A

Institutional Review Board for Human Research (IRB)

Office of Research Integrity (ORI)

Medical University of South Carolina

Harborview Office Tower

19 Hagood Ave., Suite 601, MSC857

Charleston, SC 29425-8570

Federal Wide Assurance # 1888

APPROVAL:

This is to certify that the research proposal **Pro00039593** entitled:

Exploring the under-documentation of postoperative delirium in Veterans: A qualitative study

submitted by: **Charlene Pope**

Department: **DEPT OF NURSING - MUSC**

for consideration has been reviewed by the IRB and approved with respect to the study of human subjects as adequately protecting the rights and welfare of the individuals involved, employing adequate methods of securing informed consent from these individuals and not involving undue risk in the light of potential benefits to be derived therefrom. No IRB member who has a conflicting interest was involved in the review or approval of this study, except to provide information as requested by the IRB.

Continuing Review Approval Date: **1/13/2016**

Approval Expiration: **1/12/2017**

Type: **Expedited**

Vice Chairman, IRB I - Medical University of South Carolina

* **Susan Newman, PhD, RN, CRRN**

Statement of Principal Investigator:

As previously signed and certified, I understand that approval of this research involving human subjects is contingent upon my agreement:

1. To report to the Institutional Review Board for Human Research (IRB) any adverse events or research related injuries which might occur in relation to the human research. I have read and will comply with IRB reporting requirements for adverse events.
2. To submit in writing for prior IRB approval any alterations to the plan of human research.
3. To submit timely continuing review reports of this research as requested by the IRB.
4. To maintain copies of all pertinent information related to the research activities in this project, including copies of informed consent agreements obtained from all participants.
5. To notify the IRB immediately upon the termination of this project, and/or the departure of the principal investigator from this Institution and the project.

* ***Electronic Signature****: This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*

Appendix B

Are you a Member of the Multidisciplinary Perioperative Team?

[From Primary and Specialty Care referrals to Mental Health, Pain Team, Anesthesia, Surgery, SICU and Nursing]

We need you.

A Research Study Invitation

Help us learn about documentation of postoperative delirium in the electronic medical record from your perspective.

Help the VA find ways to improve the documentation of the great care you give to our Veterans.

If you are interested in participating in a brief interview, please call Novelette Prosper at (843) 789-XXXX

Appendix C

Department of Veterans Affairs VAMC CHARLESTON	VA RESEARCH CONSENT FORM (Page 100 of 6)

Subject's Name: **Date:**

Principal Investigator: Charlene Pope, PhD, MPH, RN, FAAN

Study Title: Exploring the under-documentation of postoperative delirium in Veterans : A qualitative study

Health Care Provider Interview

A. **PURPOSE AND BACKGROUND:**

You are being asked to volunteer for a research study. This research is sponsored by the Ralph H. Johnson VA Medical Center. The purpose of this study is to explore the under-documentation of postoperative delirium among Veterans, in the electronic medical record. This study will explore topics and concerns from the perspective of the provider stakeholders. The long term goal is to understand the facilitators and barriers to the documentation of postoperative delirium, since documentation may have important clinical implications for patient care and safety. You are being asked to participate in this study because you are involved in the perioperative care of Veterans, and document your assessments, observations and treatments in the medical records. The investigators in charge of this study are Dr. Charlene Pope, Principal Investigator and Novelette Prosper, co-Investigator, and we will be responsible for answering any questions or concerns you may have about this study. This is a single site study at the VAMC in Charleston and will involve approximately 14 volunteers.

B. **PROCEDURES:**

If you agree to be in this study, the following will happen:

You will be asked to participate in a single interview, and provide answers to four open-ended, semi-structured questions. The research interviews will be conducted by the investigators who have been trained and prepared in the techniques of conducting effective qualitative interviews. You may choose either an in-person or telephone interview. If in-person, the only people in the room will be the interviewer/s and interviewee. If you choose a telephone interview, we ask that you use a room where you are alone and the door is closed. The interviews will be audio recorded, using a digital recorder capable of encryption or a secure telephone interface that transfers your recording directly to our password-protected, firewalled research server. We anticipate that the interview will take about 20-35 minutes, but feel free to provide as much insight as you deem relevant. If in-person, the

interviews will be conducted in an office space in the COIN research wing at the VAMC, where privacy and comfort can be assured. The recordings will be transcribed by a contracted transcriptionist trained to remove all names and identifiers.

C. **DURATION**

You will only meet with the researcher once. You are only asked to participate in one interview, which we anticipate will last about 20 – 35 minutes.

D. **RISKS/DISCOMFORTS:**

This study is considered minimal risk for the 14 health care providers, who are also employees at the Ralph H Johnson Medical Center. There is no intervention. The participants will be involved in a single semi-structured interview with four open-ended questions. There are very few anticipated potential risks. There should be no physical, legal or social risks, although a participant may feel some psychological risk about the information they decide to share. Although there is always a slight risk of loss of confidentiality, every effort will be made to secure the data in compliance with the VA standards and requirements. The collected data on audio recordings will be stored in a password-protected, firewalled server kept for research purposes only by the Health Equity & Rural Outreach Innovation Center (HEROIC)/COIN. Administrators in Clinical Operations do not have access to this server. The digital recorder is kept in a locked office in a locked cabinet in the Research Wing, Rm. F226. Only the investigators will have access to the equipment and data.

E. **BENEFITS:**

Although there will be no direct benefit to you from participating in this study, gaining insight into how healthcare providers view documentation of significant occurrence during patient hospitalization may have implications for improved patient safety and care. The suggestions you make may contribute to a future intervention to improve patient care.

F. **COSTS:**

Subject's Name: **Date:**

Principal Investigator: Charlene Pope, PhD, MPH, RN, FAAN

Study Title: Exploring the under-documentation of postoperative delirium in Veterans : A qualitative study

There is no charge to you for participating in this study.

G. **COMPENSATION:**

You will not be paid for participating in this study.

H. **ALTERNATIVES:**

The alternative to participation is choosing not to participate in this study.

I. **DISCLOSURE OF RESULTS:**

There is no plan to share results. If you would like to be sent a short summary of findings, please check the box below.

____ I would like to receive a summary of final findings at this email: _____

J. **EMPLOYEE PARTICIPATION**

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

K. RE-CONTACT: If you agree to be re-contacted for future questions or research within the VA, please initial by your choice below:

_____ YES, I agree to be contacted.

MUSC
IRB Number: Pro00039593
Date Approved 6/12/2015
Expiration Date: 1/20/2016

Department of Veterans Affairs VAMC CHARLESTON	VA RESEARCH CONSENT FORM (Page 103 of 6)

Subject's Name: **Date:**

Principal Investigator: Charlene Pope, PhD, MPH, RN, FAAN

Study Title: Exploring the under-documentation of postoperative delirium in Veterans : A qualitative study

_____ NO, I do not agree to be contacted.

L. PHOTOGRAPHS, VOICE AND/OR VIDEO RECORDING:

This study will collect only voice recording of the interview being taken for the research so that the interpreter can listen attentively and have the interview transcribed to capture all of the interview as accurately as possible. Only the two investigators and the transcriptionist will have access to recordings. The recordings will be encrypted and stored in a secured VA archive after the research is completed.

CONSENT

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsors and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

The VA will provide necessary medical treatment to a research subject injured by participation in a research project. This requirement does not apply to treatment for injuries that result from non-compliance by a research subject with study procedures. If you sustain an injury as a direct result of your study participation, medical care will be provided by this VA Medical Center. Financial compensation is not available for such things a lost wages, disability or discomfort due to an injury.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

Department of Veterans Affairs VAMC CHARLESTON	VA RESEARCH CONSENT FORM (Page 104 of 6)

Subject's Name: **Date:**

Principal Investigator: Charlene Pope, PhD, MPH, RN, FAAN

Study Title: Exploring the under-documentation of postoperative delirium in Veterans : A qualitative study

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, or if I have comments, concerns or complaints, I may contact: Dr. Charlene Pope 843.789.6577. I may contact the VA Medical Center's Medical Director (843.789.7200) concerning medical treatment.

If I have questions, comments, concerns or wish to voice a complaint, I may contact the VA Research Compliance Officer at (843.789.7399).

If I have any questions about my rights as a research subject in this study I may contact the Medical University of SC Institutional Review Board for Human Research at (843.792.4148).

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

Signature of Person Obtaining Consent Date Signature of Participant Date

Appendix D

Qualitative Interview Guide

1) What has been your experience with post-operative delirium (POD) in patients with substance use disorder (SUD)?
    a. Secondary Prompts: recognition; contributors; role in prevention;%
2) Studies have shown that POD is under-documented with implications for under treatment and patient safety. This lack of treatment may be a more significant problem for hypo-active POD. What factors do you think contributes to this under-documentation of POD?
3) Considering the roles of other professional stakeholders across the perioperative course, from primary care to referral across surgery to the ICU, what particular barriers to documentation may be happening from other contributors?
4) What type of actions do you think need to be taken to improve the under-documentation of post-operative delirium (POD) in patients with substance use disorder (SUD)?

Appendix E

Institutional Review Board for Human Research (IRB)
Office of Research Integrity (ORI)
Medical University of South Carolina
Harborview Office Tower
19 Hagood Ave., Suite 601, MSC857
Charleston, SC 29425-8570
Federal Wide Assurance # 1888

APPROVAL:

This is to certify that the research proposal **Pro00041319** entitled:
Substance Use Related Post-Operative Delirium: A Classification, Clinical, and Cost Analysis

submitted by: **Clara Dismuke**
Department: **CLINICAL PHARMACY-OUTCOMES SCIENCES - MUSC**
Sponsor: **VAMC**

for consideration has been reviewed by the IRB and approved with respect to the study of human subjects as adequately protecting the rights and welfare of the individuals involved, employing adequate methods of securing informed consent from these individuals and not involving undue risk in the light of potential benefits to be derived therefrom. No IRB member who has a conflicting interest was involved in the review or approval of this study, except to provide information as requested by the IRB.

Continuing Review Approval Date: **3/24/2016**
Approval Expiration: **3/23/2017**

Type: **Expedited**

Vice Chairman, IRB-I - Medical University of South Carolina
*** Susan Newman, PhD, RN, CRRN**

Statement of Principal Investigator:

As previously signed and certified, I understand that approval of this research involving human subjects is contingent upon my agreement:

1. To report to the Institutional Review Board for Human Research (IRB) any adverse events or research related injuries which might occur in relation to the human research. I have read and will comply with IRB reporting requirements for adverse events.
2. To submit in writing for prior IRB approval any alterations to the plan of human research.
3. To submit timely continuing review reports of this research as requested by the IRB.
4. To maintain copies of all pertinent information related to the research activities in this project, including copies of informed consent agreements obtained from all participants.
5. To notify the IRB immediately upon the termination of this project, and/or the departure of the principal investigator from this Institution and the project.

* ***Electronic Signature****: This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*